IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C. A. No. 06-222 (JJF)
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	

WYETH'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STRIKE THE EXPERT REPORT OF IMPAX'S PATENT LAW EXPERT, MARK E. NUSBAUM

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TABLE OF CONTENTS

	Page
TABLE OF CITATIONS	ii
NATURE AND STAGE OF THE PROCEEDING	1
SUMMARY OF ARGUMENT	1
STATEMENT OF FACTS	2
A. The Litigation	2
B. Mr. Nusbaum's Expert Report	2
ARGUMENT	6
Mr. Nusbaum's Expert Report Contains Improper Opinions On Legal Issues And Technical Topics About Which He Is Not Qualified to Testify.	6
CONCLUSION	10

TABLE OF CITATIONS

CASES

Abbott Labs. v. Syntron Bioresearch, Inc.,
2001 WL 34082555 (S.D. Cal. 2001) 9

Brooktree Corp. v. Advanced Micro Devices, Inc.,
977 F.2d 1555 (Fed. Cir. 1992) 10

Corning Inc. v. SRU Biosystems,
C.A. No. 03-633-JJF (D. Del. Nov. 5, 2004) 8

Digital Control, Inc. v. Charles Machine Works,
437 F.3d 1309 (Fed. Cir. 2006) 9

F. Hoffmann-LaRoche v. IGEN Int'l Inc.,
C.A. No. 98-318-JJF (D. Del. Oct. 24, 2000) 7

Hill v. Equitable Bank Nat'l Assoc.,
C.A. No. 82-220-CMW (D. Del. March 3, 1987) 9

L'Oreal S.A. v. Revlon Consumer Prods. Corp.,
C.A. No. 98-424-SLR (D. Del. Feb. 24, 2000) 7

Lucas Aerospace, Ltd. v. Unison Indus., L.P.,
C.A. No. 93-525-JJF (D. Del. Mar. 9, 1995) 7

Ondeo Nalco Co. v. EKA Chems., Inc.,
C.A. No. 01-537-SLR (D. Del. Mar. 21, 2003) 6

Revlon Consumer Prods. Corp. v. L'Oreal S.A.,
1997 U.S. Dist. LEXIS 4117 (D. Del. March 26, 1997) 8

Software AG v. BEA Sys., Inc.,
C.A. No. 03-739-GMS (D. Del. April 8, 2005) 8

Thorn EMI N. Am., Inc. v. Micron Tech., Inc.,
C.A. No. 92-673-RRM (D. Del. Nov. 23, 1993) 7

NATURE AND STAGE OF THE PROCEEDING

Wyeth filed this patent infringement action under the provisions of the Hatch-Waxman Act on April 5, 2006, after receiving a notice letter from Impax Laboratories, Inc. ("Impax") that it had sought approval to market a generic copy of Wyeth's highly successful Effexor®XR pharmaceutical products. The parties served opening expert reports pursuant to the Court's July 13, 2006 Scheduling Order on September 28, 2007. (D.I. 29.) Among the expert reports Impax served was a 49-page report from a purported patent law expert, Mark E. Nusbaum (the "Nusbaum report"). Wyeth has moved to strike the Nusbaum report. This is Wyeth's opening brief in support of its motion.

SUMMARY OF ARGUMENT

Despite the Court's explicit guidance in this case to the contrary, Impax seeks to rely at trial upon the opinions of a patent law expert. The Nusbaum report should be stricken because it is a legal brief submitted under the guise of an "expert report" by Mr. Nusbaum, a patent lawyer and not a person skilled in the art of the patents-in-suit. Mr. Nusbaum purports to offer opinions on inequitable conduct, including a recitation of the pertinent law, an "overview" of selected portions of the prosecution histories of the patents-in-suit, his legal opinion on inventorship and on what constitutes prior art, his views on what the alleged prior art discloses, his opinions on the materiality of prior art, and his view that Wyeth allegedly withheld material information that was inconsistent with its representations to the Examiner. To the extent Mr. Nusbaum relies on Impax's technical expert(s) on materiality, his testimony is cumulative and unhelpful because Mr. Nusbaum is not skilled in the art. To the extent Mr. Nusbaum offers his own opinions as to technical matters, he is unqualified to do so. The Nusbaum report thus contains (1) a discussion of the prosecution histories of the patents-in-suit, which this Court has

indicated it does not need; (2) improper opinions on the law regarding inventorship and what qualifies as prior art, which are ultimate issues for the Court, (3) opinions regarding materiality of information that rely heavily, if not exclusively, upon the opinions of Impax's technical experts, and (4) technical topics on which Mr. Nusbaum has no expertise. Needless to say, Wyeth strenuously disagrees with the substance of Mr. Nusbaum's opinions, as well as with the opinions of the experts upon whom he allegedly relies. But Wyeth seeks to strike the Nusbaum report because no part of it provides any admissible or helpful information to the Court in this bench trial.

STATEMENT OF FACTS

A. The Litigation

The patents at issue in this case, U.S. Patent Nos. 6,274,171 B1 ("'171 patent"), 6,403,120 B1 ("'120 patent"), and 6,419,958 B2 ("'958 patent"), relate to the use of once-a-day extended release formulations of venlafaxine hydrochloride to provide therapeutic blood plasma concentrations of the drug having specified pharmacokinetic characteristics and the benefit of diminished incidences of nausea and vomiting as compared to the side effects resulting from an immediate release formulation of venlafaxine.

B. Mr. Nusbaum's Expert Report

Mr. Nusbaum asserts in his report that he is a lawyer with extensive experience at the United States Patent and Trademark Office ("PTO") as a patent examiner and as a member of the Board of Patent Appeals and Interferences. (Ex. A at 1-2.) Mr. Nusbaum has a degree in electrical engineering and has expertise in the area of computer system architecture, computer programming, and mathematical algorithm related inventions. (Ex. A at Tab 1.) Mr. Nusbaum is not an expert in pharmaceutical dosage formulations, pharmaceutical clinical trials, the

treatment of psychiatric disorders, or other related arts and has no expertise in the subject matter of the patents at issue in this case.

Mr. Nusbaum nonetheless offers opinions both on the law and on the ultimate issue of whether Wyeth engaged in inequitable conduct before the PTO during the prosecution of the patents-in-suit, including opinions on what the prior art discloses, the materiality of the references, and his interpretation of clinical data, despite having no background in the area.

After a discussion of some basic information regarding patent law in general (Ex. A at ¶¶ 6-25), Mr. Nusbaum provides his own, but far from complete, overview of the prosecution histories of the patents-in-suit (*id.* at ¶¶ 26-76). Mr. Nusbaum then offers several pages about "a patent applicant's duty of disclosure owed to the PTO" as "foundational testimony for the materiality-related opinions" he provides (*id.* at ¶ 77). In doing so, he goes through his view of the development of the law since 1945, citing various cases and Patent Office rules (*id.* at ¶¶ 77-88).

The Nusbaum report also is replete with opinions on materiality, and on what the Examiner would have done if certain information had been disclosed to him. The substance of Mr. Nusbaum's opinions can be gleaned from the main headings of his report under the Duty of Disclosure (section IV):

- "A. Information Inconsistent With Arguments For Patentability Regarding The Eight And Twelve Week Studies Should Have Been Disclosed To The PTO" (Ex. A at 29);
- "B. Material Information Regarding Alza Prior Art Was Not Disclosed To The PTO" (*id.* at 38); and
- "C. Information Material To Whether The '171 and '120 Patents Named The Correct Inventors Was Not Disclosed To The PTO." (*id.* at 41.)

Mr. Nusbaum also offers opinions on what would purportedly "constitute[] an argument for patentability" (*id.* at ¶¶ 93-94), and on whether Wyeth's arguments about clinical data were accurate in light of its representations to the PTO. He states, for example[1]:

- "In my opinion, **information would be inconsistent with the argument** that 'Venlafaxine ER showed a statistically significant improvement' . . . if, for example, such information evidences that the two eight-week and one 12-week studies a) did not show a statistically significant improvement over conventional venlafaxine hydrochloride and/or b) no comparison was made with respect to conventional venlafaxine hydrochloride" (*id.* at ¶ 98).

But to assess whether there are any such inconsistencies, Mr. Nusbaum relies almost entirely upon Impax's technical experts to interpret the quoted passage and to interpret the clinical data. [*See id.* at ¶¶ 100-103; 106 (expressly indicating Mr. Nusbaum's reliance on technical experts)]. For example:

- **Relying on Impax's technical expert, in my view, the PTO should have been informed** that no direct comparison with conventional venlafaxine hydrochloride tablets was made" (*id.* at ¶ 102).

- **"[R]elying on Impax's technical expert,** although study 208 did directly compare patients receiving venlafaxine hydrochloride extended release with patients receiving conventional venlafaxine hydrochloride immediate release tablets, **the data from study 208 did not establish statistically significant improvement** with respect to level of nausea and incidence of emesis." (*id* at ¶ 103).

- "**Relying on Impax's technical expert,** this Cunningham article specifically discusses the results from study 208 and **evidences that there was no statistically significant improvement evidenced in study 208**, when venlafaxine extended release was compared with conventional venlafaxine hydrochloride tablets." (*id.* at ¶ 106.)

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[1] Emphasis in the quoted material is added unless otherwise noted.

Based on his reliance on Impax's technical expert's review of the clinical data, Mr. Nusbaum opines that "[s]ince such information is inconsistent with the argument for patentability proffered in the specifications of the patents-in-suit, **such information is material and should have been disclosed to the PTO**." (*id.* at ¶ 107.)

Mr. Nusbaum offers similar opinions with respect to the alleged nondisclosure of the alleged Alza prior art. For example, Mr. Nusbaum opines that:

- **"[R]elying on Impax's technical expert, material information** regarding Alza's venlafaxine extended release formulation **was not disclosed to the PTO**" (*id.* at ¶ 110).

- "In my opinion, **relying on Impax's technical expert**, undisclosed information regarding the properties of the Alza Venlafaxine extended release prior work is material and **should have been disclosed to the PTO**." (*id.* at ¶ 115.)

To the extent, then, that Mr. Nusbaum purports to rely upon the opinions of Impax's technical experts, he has no non-cumulative opinions to offer on these technical matters.

In some cases, Mr. Nusbaum apparently offers technical opinions of his own, despite being clearly unqualified to do so. For example:

- "The Alza '589 PCT **application failed to disclose** properties inherent in the Alza prior art formulation that are claimed in the patents-in-suit. For example **the '134 study discloses** an Alza venlafaxine extended release formulation that produces a peak blood plasma level in patients in about six hours." (*id.* at ¶ 117; *see also* ¶ 130.)

Such unqualified opinions on highly technical subject matters can provide no assistance to the Court.

Mr. Nusbaum also provides legal opinions, which amount to nothing more than attorney argument, on what constitutes prior art (*id.* at ¶ 114), how the examiner would have responded to the allegedly withheld information (*id.* at ¶¶ 112, 188, 121), and on issues of inventorship (*id.* at ¶¶ 134-35).

Beyond offering opinions on the ultimate issues of case, Mr. Nusbaum also recites the relevant law, which he then purports to apply to the facts: for example, anticipation and obviousness (*id.* at ¶¶ 13-14, 86, 112-14, 118, 121), provisional patent application practice (*id.* at ¶¶ 15-20), the duty of disclosure and the standards of materiality (*id.* at ¶¶ 77-85, 91, 111), what constitutes prior art (*id.* at ¶¶ 114, 117), inventorship (*id.* at ¶¶ 124-25) and the differences between PTO practice and the court system (*id.* at ¶ 25). He also offers opinions about patent office practice and procedures, such as the training of examiners (*id.* at ¶¶ 6-9, 95-97, 123-24), the references and resources available to them (*id.* at ¶¶ 11-12, 21-24, 126), and the time constraints on them (*id.* at ¶ 21). He also provides, in his own recitation of the prosecution histories of the patents in suit (*id.* at ¶¶ 27-76), opinions about the representations the examiner purportedly "would have noted" in the specifications (*id.* at ¶¶ 28, 35, 45).

ARGUMENT

Mr. Nusbaum's Expert Report Contains Improper Opinions On Legal Issues And Technical Topics About Which He Is Not Qualified to Testify.

It is well-established in this district that opinions by legal experts on issues of law are inadmissible. Judge Robinson's *Guidelines: Legal Expert Testimony in Patent Cases* (Ex. B) specify:

> "Expert" legal testimony (as opposed to technical testimony) on such substantive issues as invalidity (by anticipation, obviousness, on-sale bar, prior conception, etc.) and claim construction and infringement, generally is not admitted as descriptions of the law and instructions on the law are matters for the court.

See also Ondeo Nalco Co. v. EKA Chems., Inc., C.A. No. 01-537-SLR, slip op. at 9 (D. Del. Mar. 21, 2003) (striking expert report where patent law expert purported to opine "as to how the

United States Patent and Trademark Office would have responded had certain prior art been disclosed to it during the prosecution of the '805 patent") (Ex. C); *L'Oreal S.A. v. Revlon Consumer Prods. Corp.*, C.A. No. 98-424-SLR, Order at 3 (D. Del. Feb. 24, 2000) (noting that patent law expert would not be permitted to offer "an opinion on law or an opinion as to 'the thoroughness of the consideration of those issues' considered by the examiner") (Ex. D); *Lucas Aerospace, Ltd. v. Unison Indus., L.P.*, C.A. No. 93-525-JJF, Order at 2 (D. Del. Mar. 9, 1995) (patent law experts may not "draw inferences or make statements or conclusions about the patent law of the case") (Ex. E); *Thorn EMI N. Am., Inc. v. Micron Tech., Inc.*, C.A. No. 92-673-RRM, Tr. at 32, 34 (D. Del. Nov. 23, 1993) (The Court does not "allow opinions on issues of law" or opinions "on what the significance may be on certain things that took place at the patent office") (Ex. F).

This Court also has expressed the view that patent law experts are unhelpful. This Court stated in *F. Hoffmann-LaRoche v. IGEN Int'l Inc.*, C.A. No. 98-318-JJF, Tr. 64 (D. Del. Oct. 24, 2000) (Ex. G) that the Court "very consistent[ly]" excludes patent law experts in both bench and jury trials:

> If you want assistance in preparing the case, hire him as a special litigation counsel. If you want him to come under the rules of an expert witness, you are in a different ballgame. And in this district, when you get into that patent law/expert/et cetera area, we have a very consistent view. And the view is that they are not helpful. And not only do we mostly exclude them on Bench trials, but in jury trials they are so severely limited, I can't figure out why anybody continues to propose them.

Indeed, this very issue came up at the February 7, 2007 status conference in response to Impax's request for the Court's guidance on patent law experts. This Court stated that it is "the legal expert, and it's unlikely that I need one in this case. So unless there's something discrete and

extraordinary, we wouldn't have one." (D.I. 87, Tr. at 15.) There is no discrete or extraordinary issue in this case requiring a patent law expert.

Judge Robinson's Guidelines also provide that expert testimony regarding patent practice and procedure "is not required and will not be permitted except in the case of extraordinary circumstances." *See also Corning Inc. v. SRU Biosystems*, C.A. No. 03-633-JJF, Order at 2 (D. Del. Nov. 5, 2004) (patent lawyer's "report and proposed testimony deal[ing] primarily with internal patent office procedures" excluded) (Ex. H).

Patent law experts also are not permitted to offer opinions the issue of inequitable conduct. *See Revlon Consumer Prods. Corp. v. L'Oreal S.A.*, 1997 U.S. Dist. LEXIS 4117, *7-8 (D. Del. March 26, 1997) (precluding patent law expert from offering opinions on inequitable conduct because such testimony "would usurp the respective functions of the jury and the Court" and further noting that the holding precluded, among other things, the proposed testimony concerning the "duties and responsibilities of an inventor, his or her attorney or agent, and others substantively involved in the preparation and prosecution of a patent application in the PTO. . .") (footnote omitted).

In his expert report, Mr. Nusbaum plainly offers impermissible legal opinions on the duty of disclosure, inventorship, what constitutes "prior art," inequitable conduct, whether Wyeth withheld information from the PTO during the prosecution of the patents in suit, the materiality of the allegedly withheld information, and how a person of ordinary skill in the art would interpret the patents and prior art. Judge Sleet recently granted a motion to exclude Mr. Nusbaum's testimony about the materiality of certain information and what the examiner would have thought. *Software AG v. BEA Sys., Inc.*, C.A. No. 03-739-GMS, Tr. 20 (D. Del. April 4, 2005) ("as you know, being in this district all the time, none of the four judges who hear these

cases routinely generally permit this type of testimony" because "the Court is presumed to be the patent law expert"). (Ex. I.)[2]

In addition to legal opinions, Mr. Nusbaum offers opinions about the subject matter of the patents-in-suit even though he is not one skilled in the relevant art. Mr. Nusbaum purports to opine as to what certain prior art discloses, the proper interpretation of the clinical trial results, and to reach conclusions about inventorship, and then to compound those unqualified opinions with the view that this information was material and should have been disclosed to the patent examiner. Because Mr. Nusbaum lacks the qualifications necessary to opine on the technology of the patents-in-suit, his testimony about the materiality of information that was allegedly withheld from the PTO is unreliable and should be precluded.

The standards by which information may be deemed material require an understanding of the significance of technical information to one of skill in the art. *See Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006). Thus, only one skilled in the art can offer opinions about materiality. *See Abbott Labs. v. Syntron Bioresearch, Inc.*, 2001 WL 34082555, at *6 (S.D. Cal. 2001) (If expert testimony is used to prove materiality, the expert must be qualified "to voice the understanding of one skilled in the art.").

Mr. Nusbaum also offers opinions about the amount of time examiners spend and the information available to them. (Ex. A at ¶ 21-24). A patent examiner, however, is presumed

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[2] In *Hill v. Equitable Bank Nat'l Assoc.*, C.A. No. 82-220-CMW (D. Del. March 3, 1987) (Ex. J) a securities case, Judge Wright excluded the testimony of a law professor about whether alleged omissions and misrepresentations were material, because it was inappropriate for a witness "to testify as to the legal significance of a particular set of facts."

to have performed his or her job correctly. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1992).

There is simply nothing in Mr. Nusbaum's report that will be helpful to the Court in this bench trial. The Court does not need an "expert" to explain the legal requirements or the facts, or to tell it what is material or what an examiner would have done. The trial lawyers can make those arguments and the Court can decide them without assistance from Mr. Nusbaum.

CONCLUSION

For the foregoing reasons, Wyeth's motion to strike the expert report of Impax's patent law expert, Mark E. Nusbaum, should be granted.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on October 12, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff,	)	Civil Action No. 06-222 JJF
v.	)	
IMPAX LABORATORIES, INC., Defendant.	)	

EXPERT REPORT OF MARK E. NUSBAUM

In accordance with F.R.C.P. 26(a)(2), the following is my written report detailing the subject matter areas and opinions about which I expect to testify to in the above-identified litigation if called upon to do so.

I. BACKGROUND AND QUALIFICATIONS

1. I may testify regarding my qualifications, background and experience in the field of Patent & Trademark Office ("PTO") practice. I received a B.S. degree in Electrical Engineering from the University of Maryland in 1969. I received a Juris Doctor degree from American University in 1974. I became an Examiner in the U. S. PTO in 1969. I received the authority to grant or deny patents over my own signature in 1975 and became a Senior Examiner in 1977. During this time frame, I personally examined in the vicinity of 750 to 1000 patent applications.

2. In 1980, I was appointed as a Supervisory Patent Examiner to manage a group of patent examiners (referred to as an "art unit") and was responsible for training examiners, evaluating examiner work product quality, granting or denying patent

protection, and assisting junior examiners in making patentability decisions. During the latter 1970's and early 1980's, I taught PTO in-house patent examiner initial training courses to examiners having electrical, mechanical, and chemical technological backgrounds and lectured at the PTO's patent academy.

3. In 1983, I was appointed as an Examiner-in-Chief and member of the Board of Patent Appeals and Interferences ("the Board") in the PTO. The Board is a quasi-judicial appellate body that hears appeals in panels of at least three members from decisions of primary examiners adverse to patent applicants. A Board panel reviews the record made during the examination of an application, receives briefs from counsel and examiners, conducts hearings and prepares written opinions. The Board's decisions constitute final agency determinations with respect to substantive questions of patent law. They are reviewable by the United States Court of Appeals for the Federal Circuit or by the United States District Court for the District of Columbia, whose decisions, in turn, are reviewable by the Court of Appeals for the Federal Circuit.

4. My work as a member of the Board required an understanding of patent claims and how they should be construed, as well as an understanding and application of the pertinent statutes, precedents, rules, and other regulations regarding the examination of applications for issuance of United States Letters Patents. While on the Board, I participated in approximately 500 to 750 appeals. Although the majority of these appeals involved electrical technology, a significant number involved mechanical, electromechanical or chemical technologies.

5. In 1986, I resigned from the PTO to become a member of the Nixon and Vanderhye intellectual property law firm in Arlington, Virginia. I specialize in all phases

of patent application preparation and prosecution and have served as an expert witness in PTO practice and patent law in many patent infringement litigations. During my career, I have been involved in numerous aspects of patent practice, including the drafting and prosecution of patent applications, evaluating prior art references and preparing numerous patentability, validity and infringement opinions. I have prosecuted hundreds of patent applications and I have reviewed hundreds of prosecution histories of other applications. Over my career, I have had occasion to review thousands of claims in patents and patent applications in order to determine their meaning, to compare them with the prior art, to compare their scope with the specification disclosure and/or to compare them with accused products or processes. For further details, my curriculum vitae is attached as Exhibit 1 hereto.

II. PATENT OFFICE PRACTICE -- RELATED OPINIONS AND BASIS THEREFOR

A. GENERAL

6. I may testify about patent examining practice before the PTO. I may testify as to the nature of a patent grant, and the various parts of a patent application, including the specification, claims, and oath. I may testify about how patent examiners are trained with respect to the various patent application disclosure requirements. For example, patent examiners are trained that, as of the original filing date, the patent specification must be set forth in such full, clear, concise and exact terms so as to enable a person skilled in the art to make and use the claimed invention without resorting to undue experimentation.

7. Additionally, the patent specification must set forth, as of the original filing date, the best mode contemplated by the inventor for carrying out the claimed invention. Examiners are trained that the "best mode" requirement precludes a patent applicant from securing patent protection for a claimed invention while at the same time concealing the inventor's contemplated best mode of practicing the claimed invention. The specification must also satisfy the written description disclosure requirement and provide adequate support for later claimed subject matter. The "written description" requirement is separate and distinct from the "enablement" and "best mode" requirements. The purpose of the "written description" requirement is broader than to merely explain how to "make and use" the invention. With respect to claims added after the original filing date, the original disclosure must convey with reasonable clarity to those skilled in the art that, as of the filing date, the inventors were in possession of the later claimed invention.

8. At least in part because patent examiners are charged with the responsibility of assessing the sufficiency of a patent application disclosure on these grounds, examiners are expected to carefully review the patent application disclosure.

9. Patent examiners are trained that a patent claim is a single sentence definition of the metes and bounds of an applicant's invention, defining the scope of legal protection to which a patentee is entitled. Patent examiners are trained that claims are not to be interpreted in a vacuum, but rather must be interpreted in light of the patent specification. Examiners are required to give claim language its broadest reasonable interpretation consistent with the specification. A patent claim must be set

forth with a reasonable degree of precision and particularity such that the metes and bounds of the invention are reasonably circumscribed.

10. I may testify as to how a patent examiner examined a patent application including studying the original patent application specification and original claims, searching for relevant prior art patents and publications and generating Office Actions. I may testify that patent applicants respond to an objection or rejection in an Office Action by attempting to convince the examiner that the objection or rejection was improper and/or by amending the patent claims. In response, the examiner decides whether to allow, or finally reject, the patent application. If a final Office Action is rendered, an applicant may appeal to the PTO's Board of Patent Appeals and Interferences.

11. Patent examiners are guided in their examination practice by the PTO's Manual of Patent Examining Procedure (MPEP). The MPEP is a compilation of patent examining guidelines used as a reference work on the practice and procedures relative to the prosecution of patent applications before the PTO.

12. With respect to searching the prior art, I will testify that in the PTO the chemical, electrical and mechanical technologies were during the pendency of the patents-in-suit (and are today) divided into numerous generic classes of technology. Each class is divided into more specific subclasses into which issued patents are classified. During the time frame in which the patents-in-suit was examined, patent examiners had access to both a manual and computer-based search system. Patent examiners had access to a complete set of all U.S. patents. To a much lesser degree, patent examiners had access to foreign patents and printed publications. Patent

examiners did not typically have access to information about products that were in public use or on sale. Under certain circumstances, patent examiners are precluded from allowing a patent application where the claimed subject matter or an obvious variation of the claimed subject matter had been sold or offered for sale more than one year prior to the application filing date. Patent examiners did not then and do not today typically have access to public use and on-sale information, product brochures or operation manuals. The PTO examiners necessarily rely on patent applicants complying with their duty of disclosure so that they will have the opportunity to consider such information.

13. A patent examiner's rejections are typically based upon anticipation under 35 USC §102, obviousness under 35 USC §103 or failure to comply with 35 USC §112, which governs, *inter alia*, the content of the patent specification. To properly reject a patent claim based on anticipation, it is necessary that a single prior art reference, device, or practice include a counterpart to each and every claimed limitation, either expressly or under principles of inherency.

14. With respect to obviousness, examiners were trained to perform the analysis set forth in Graham v. John Deere, 383 U.S. 1, 86 S. Ct. 684 (1966) and its progeny. Thus, for example, examiners were required to determine the scope and content of the prior art; ascertain the differences between the prior art and the claims at issue; resolve the level of ordinary skill in the pertinent art; and consider objective evidence of obviousness or nonobviousness.

15. I may testify as to PTO provisional patent application practice. See M.P.E.P. 201.04 (1997). Beginning in June of 1995, applicants were authorized to file

provisional applications to provide a mechanism for applicants to quickly and inexpensively file a patent application. Under the provisions of 35 U.S.C. 119(e), applicants are entitled to gain the benefit a provisional application filing date under appropriate circumstances. The domestic priority period does not count in the measurement of the 20-year patent term. See 35 U.S.C. 154(a)(3). Thus, domestic applicants are placed on equal footing with foreign applicants with respect to the patent term.

16. The parts of a provisional application that are required to be present are set forth in 37 CFR 1.51(a)(2) and MPEP 601.01 and 601.01(b). The filing date of a provisional application is the date on which (1) a specification which complies with 35 U.S.C. 112, first paragraph, and (2) any drawing required by 37 CFR 1.81(a) are filed in the name of the actual inventor or inventors as required by 37 CFR 1.41. A provisional application must also include a cover sheet identifying the application as a provisional application. Otherwise, the application will be treated as an application filed under 37 CFR 1.53(b)(1).

17. Provisional applications differ from a regular U.S. patent application in that (1) no claim is required in a provisional application, (2) no oath or declaration is required in a provisional application, and (3) provisional applications will not be examined for patentability, placed in an interference, or made the subject of a statutory invention registration.

18. A provisional application will automatically be abandoned 12 months after its filing date and will not be subject to revival to restore it to pending status thereafter.

A provisional application is not entitled to claim priority benefits based on any other application under 35 U.S.C. 119, 120, 121, or 365.

19. In order to obtain the benefit of a provisional application filing date under 35 U.S.C. §119(e)(1), it is necessary for the specification of the provisional application to disclose the invention in the manner provided by 35 U.S.C. §112, first paragraph.

20. The "written description" requirement of 35 U.S.C. §112, first paragraph, is among the disclosure requirements which must be satisfied in order for a provisional application to adequately support a non-provisional claimed invention. As indicated above, the purpose of the written description requirement is broader than to merely explain how to make and use the claimed invention. An applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the later claimed invention. The provisional application disclosure must show that the inventor invented each feature that is included as a claim limitation. It is not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure, but rather whether the application necessarily discloses that particular set of claim features.

21. Patent examiners operate under time constraints dictated by examining productivity goals. In even the most complex technological areas in the PTO, examiners are expected to examine an application from start to finish at an average in the range of 2 to 3 days (which includes time spent reviewing the originally filed specification and claims, searching the prior art, reviewing and understanding the cited prior art, comparing the prior art with the claimed subject matter, preparing office actions, and reviewing the applicant's responses).

22. Patent examiners in a typical patent application prosecution have no access to independent technical expert testimony and, therefore, do not have the opportunity to consult with technical experts in any given technological field. The examination process for a typical application in the PTO is strictly an *ex parte* proceeding in which opponents to a patent have no input.

23. The PTO has no in-house testing facility. Thus, PTO examiners rely on patent applicants to fairly present any test data submitted during the prosecution of a patent application.

24. There are a number of patent validity-related issues that cannot be analyzed by a patent examiner due to lack of information relating to such issues. If a patent examiner is not aware of critical information relating to a validity issue, nothing will trigger the need to consider such an issue. For example, although a patent should not issue unless the correct inventors are named, a patent examiner has no way of independently investigating inventorship. Similarly, if another patent applicant actually came up with the claimed invention prior to the application at issue, unless a formal proceeding called an interference is initiated in the PTO, there is no way that the PTO will have the necessary information to make any determination as to who was the first to invent. Further, the PTO typically does not have information with respect to best mode issues, or on-sale or public-use related activities that can operate to invalidate a patent under certain conditions. Patent examiners rely on patent applicants complying with their duty of disclosure by disclosing any such material information of which they are aware.

25. I may testify that patent examiners are trained that the federal court system is an integral part of the U.S. patent system. A federal court considers patent infringement issues which are not considered by the PTO. The fact finder in a federal court patent litigation hears evidence relating to patent validity that is typically not available to a PTO examiner. Patent examiners are trained that patents once issued are accorded a presumption of validity. Patents, however, may be found to be invalid in a federal court, if clear and convincing evidence establishes invalidity, even if such evidence has been considered by the PTO.

III. PROSECUTION HISTORIES OF THE PATENTS-IN-SUIT

26. I will testify about the prosecution histories before the PTO of U.S. Patent Nos. 6,274,171 (the '171 patent); 6,403,120 (the '120 patent); and 6,419,958 (the '958 patent). I may testify regarding information contained on the PTO application file jackets, describe pre-office action activities such as the prior art search and describe communications between the applicants and the PTO in the patent applications which matured into the patents-in-suit including the official actions and responses described below.

A. PROSECUTION HISTORY OF U.S. PATENT NO. 6,274,171

1. PROSECUTION HISTORY OF U.S. APPLICATION SERIAL NO. 08/821,137

27. Application Serial No. 08/821,137 was filed on March 20, 1997, naming Deborah Sherman as the sole inventor. The application claimed the benefit of provisional application Serial No. 60/014,006, which was filed on March 25, 1996. The application included 10 pages of specification (as did the provisional application) and 10 original claims including independent claim 1 directed to an encapsulated, extended

release formulation of venlafaxine hydrochloride comprised, *inter alia*, of a hard gelatin capsule containing spheroids comprised of various ingredients, independent claim 6 directed to a film coating composition, independent claim 7 directed to an extended release formulation of venlafaxine hydrochloride for once daily administration and independent method claims 9 and 10.

28. One of the Examiner's first tasks in examining the application is to read and study the original patent specification to ensure the specification complies with disclosure requirements and to gain a clear understanding of the original claims. In the course of undertaking such a review, the Examiner would have noted the representation regarding the "BRIEF DESCRIPTION OF THE INVENTION" that "venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." Original specification at page 3. Provisional application specification at page 3.

29. In a July 30, 1997 Information Disclosure Statement, various prior art U.S. patents were brought to the Examiner's attention.

30. In a July 30, 1997 telephone interview between the applicants' representative and the Examiner, claims 6, 9 and 10 were discussed in light of Upton et al. (U.S. Patent No. 5,506,270). The Examiner noted that it was "[a]greed to amend claims 9 and 10 to depend upon claim 1 to avoid rejection over Upton which discloses extended release venlafaxine at col. 5, lines 25-27."

31. In an August 5, 1997 Notice of Allowability, the Examiner allowed claims 1-5 and 7-10. In an associated restriction requirement, the applicants were required to elect between claims 1, 5, 7 and 10, drawn to a composition and method, classified in

class 424, subclass 461 and claim 6, drawn to a film coating, classified in class 427, subclass 3. Applicants' representative, Robert Boswell, elected on July 30, 1997 to prosecute claims 1-5 and 7-10 in the subject application.

32. In an associated Examiner's amendment, claim 6 was canceled and claims 9 and 10 were amended.

33. In a February 3, 1998 Communication, application Serial No. 08/821,137 was abandoned for failure to pay the issue fee.

2. PROSECUTION HISTORY OF U.S. APPLICATION SERIAL NO. 08/964,328

34. Application Serial No. 08/964,328 was filed on November 5, 1997, naming Deborah Sherman, John Clark and John Lamer as joint inventors. The application was filed as a continuation-in-part of application Serial No. 08/821,137. Application Serial No. 08/964,328 added new subject matter to the prior filed application. The application was filed with 18 original claims, including independent claim 1 directed to an encapsulated extended release formulation of venlafaxine hydrochloride, comprising, *inter alia*, a hard gelatin capsule, independent claim 11, directed to an encapsulated extended release formulation of venlafaxine hydrochloride for once daily administration, comprising, *inter alia*, spheroids, independent method claim 13 directed to a method for providing therapeutic blood plasma concentration of venlafaxine over a 24-hour period with diminished instances of nausea and emesis, and independent method claim 14 directed to a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride.

35. As indicated above, one of the Examiner's first tasks in examining the application is to read and study the original patent specification to ensure the specification complies with disclosure requirements and to gain an understanding of the original claims. In the course of undertaking such a review, the Examiner would have noted the representation regarding the "BRIEF DESCRIPTION OF THE INVENTION" that "venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." Original specification at page 3.

36. In a February 13, 1998 Information Disclosure Statement, various prior art U.S. patents were disclosed to the PTO.

37. In an August 17, 1998 Supplemental Information Disclosure Statement, further prior art was disclosed to the PTO including the Alza PCT application WO 94/27589.

38. In October 14, 1998 Office Action, claim 15 was rejected under 35 U.S.C. §112, first paragraph, for failing to provide an enabling disclosure. The Examiner took the position that the specification does not provide an enabling disclosure for 940% microcrystalline cellulose. The Examiner further rejected claims 17 and 18 as being indefinite in light of the limitation "the spheroids."

39. With respect to the prior art, the Examiner rejected claim 1 under 35 U.S.C. §103 as being unpatentable over McAinsh (U.S. Patent No. 4,138,475) in view of Wong (U.S. Patent No. 5,552,429). The Examiner took the position that:

> McAinsh et al. shows a hard gelatin capsule comprised spheroids coated with a mixture of ethyl-cellulose and hydroxypropylmethyl-cellulose. The active agent propranolol is blended with micro-crystalline cellulose. See Abstract, example and claim 1. The reference does not

> show venlafaxine. Wong et al. is relied on for teaching extended release dosage forms comprised of the same ingredients as McAinsh et al. including the drugs venlafaxine and propranolol. See column 4, lines 7-10, column 6, lines 54-55, column 7, lines 18-22, formulation 5. To use the venlafaxine of Wong et al. in the McAinsh et al. capsule with a reasonable expectation of success would have been obvious to one of ordinary skill in the art. The motivation being a desire to obtain optimum drug and efficacy over a prolonged period of time while improving patient compliance by reducing the number of dosages required.

October 1998 Office Action at pages 3 and 4.

40. The Examiner allowed claims 11, 13 and 14, and indicated that claims 2-10, 12 and 16 would be allowable if rewritten in independent form.

41. In an April 16, 1999 Amendment, the applicants canceled claim 1, amended claims 2, 3, 5-8, 11, 15-18 and added new claims 19-26. The applicants indicated that canceled claim 1 was replaced by new claim 23. The applicants argued that claim 23 was patentable over the cited art by arguing:

> [c]anceled Claim 1 is replaced by Claim 23 which is directed to the gravamen of Applicants' invention, namely, the coated spheroids containing venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose for extended release. New Claims 24 and 25, dependent upon Claim 23 are directed to a dosage form in a capsule and in a hard gelatin capsule, respectively, containing the coated spheroids of Claim 23. New claim 26 is directed to the extended release dosage form of Claim 23 having the disclosed dissolution rate.
>
> <u>Rejection of Claim 1 (new Claim 23) for obviousness</u>
>
> The rejection of Claim 1 under 35 USC 103 for obviousness over McAinsh et al. (US Patent 4,138,475) in view of Wong et al. (US 5,552,429) is respectfully traversed. (Claim 1 has been canceled and replaced by new Claim 23.) McAinsh is relied upon for showing a hard gelatin capsule comprised of spheroids containing an admixture of the active ingredient propranolol HCl and microcrystalline cellulose and coated with ethyl cellulose and hydroxypropylmethyl cellulose. As noted by the Examiner, venlafaxine is not mentioned in this disclosure. (Additionally, venlafaxine and propranolol are not structurally related.) Wong et al. is relied upon for teaching extended release dosage forms

comprised of the same ingredients as McAinsh et al. including the drugs venlafaxine and propranolol.

The Examiner's statement of the teaching of Wong et al. is incorrect. Wong et al. is not directed to providing sustained/extended release compositions and only discloses the existence of particular sustained release compositions for pindolol. Rather, Wong et al. discloses a method of potentiating the action of a first component chosen from fluoxetine, venlafaxine, milnacipran, and duloxetine in increasing the availability of serotonin, norepinephrine and dopamine in the brain, comprising administering such first component in combination with a second component chosen from the group consisting of alprenolol, WAY 100135, spiperone, pindolol, (S)-UH-301, penbutolol, propanolol, tertatolol, and compounds of a given structural formula I. (See col. 1, line 65, through col. 2, line 10.) In fact, the dose of venlafaxine indicated in col. 6, lines 54-55, is from about 10 to about 150 mg once-thrice/day; preferred, from 25 to 125 mg thrice/day.

At page 7, lines.33-65, Wong et al. discusses the preference of combining the two components in one dosage form. However, they state that this may not be possible for the desired combination. At col. 8, lines 35-53, i.e. after the disclosure of referencing specific pindolol sustained release formulations, Wong et al. states that the second component may possibly be used in its sustained release formulation in its combination with the first component in order to provide substantially constant blood levels of the second component. Moreover, under "Benefits of the Invention", at col. 13, lines 32-44, Wong et al. states that the invention provides a more rapid onset of action and is usually provided by treatment of fluoxetine or duloxetine alone. Thus, it is clear that it is not an object of Wong et al. to provide new sustained release formulations of the first and second components alone or combined.

Finally, none of the 8 exemplified formulations includes venlafaxine. The two formulations including microcrystalline cellulose, that is, Formulations 4 and 5, include substantial portions of at least one other pharmaceutical excipient-but not hydroxypropylmethylcellulose.

For these reasons, the teaching of Wong et al. is deemed not particularly relevant to Applicants' invention of coated spheroids of venlafaxine hydrochloride for extended release.

Further, the teaching of a sustained release formulation of microcrystalline cellulose and propranol hydrochloride in McAinsh et al. is not deemed sufficiently relevant to venlafaxine because the two compounds are not structurally related. Moreover, there is a tremendous difference in water solubility of the two compounds. The water solubility of

> propanolol hydrochloride is 93 mg/ml, whereas that of venlafaxine hydrochloride is 574 mg/ml - i.e. 6 fold greater. Therefore, Applicants' invention, as claimed in claims 23, 2 and 15, is indeed unobvious.

April 16, 1999 Amendment at pages 6 and 7.

42. In a July 21, 1999 Office Action, the Examiner rejected claims 23-26 under 35 U.S.C. §103 as being unpatentable over McAinsh in view of Wong. The Examiner took the position that:

> The claims are rejected for the reasons set forth in Paper No. 7 as applied to now canceled claim 1. Applicants' arguments filed April 16, 1999 have been fully considered but they are not persuasive. Applicants state that, as noted by the examiner, venlafaxine is not mentioned in the McAinsh et al. reference. Applicants further state that venlafaxine and propranolol are not structurally related. This is true, however the only difference in the McAinsh et al. reference is that the only drug disclosed is propranolol. Wong et al. is not relied on for showing a sustained release dosage form of either drug, but is relied on for teaching that it is known the two drugs can be combined and administered together. To one skilled in the art with the disclosure of both McAinsh et al. and Wong et al. displayed together it would be reasonable to expect possible combinations. It would have been obvious to one of ordinary skill in the art to use the Wong et al. venlafaxine in the McAinsh et al. sustained release dosage form comprised of spheroids. Propranolol common to both McAinsh et al. and Wong et al. can be combined with venlafaxine. A combination of both in a sustained release dosage form would increase patient compliance when the need arises to administer the two together. The scope of applicant's claims in reciting comprising does not exclude additional active agents. A dosage form of propranolol alone or propranolol and venlafaxine meets the limitations of applicants' claims.

July 21, 1999 Office Action at pages 2-3.

43. In a February 16, 2000 Notice of Abandonment, the application was abandoned due to applicants' failure to timely respond to the July 21, 1999 Office Action.

3. PROSECUTION HISTORY OF U.S. APPLICATION SERIAL NO. 09/488,629 THAT MATURED INTO THE '171 PATENT

44. The '171 patent was filed on January 20, 2000 as application Serial No. 09/488,629, naming Deborah Sherman, John Clark, John Lamer and Steven White as joint inventors. The application was filed as a continuation-in-part of abandoned application Serial No. 08/964,328. The '171 patent was assigned to American Home Products, Corp. The application was filed with 22 original claims, including independent claim 1 directed, *inter alia*, to an encapsulated extended release formulation of venlafaxine hydrochloride; and independent method claims 21 and 22, directed to a method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis and a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride, respectively.

45. As indicated above, one of the Examiner's first tasks in examining an application is to read and study the original patent specification to ensure the specification complies with disclosure requirements and to gain an understanding of the original claims. In the course of undertaking such a review the Examiner would have noted the above-identified representation regarding the "Brief Description Of The Invention" that "venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." See the original application Serial No. 09/488,629 specification at page 4.

46. In July 16, 1999 Supplemental Information Disclosure Statement, the applicants brought two patent publications to the Examiner's attention, dated October 16, 1997 and October 1, 1997, respectively.

47. In an April 24, 2000 Information Disclosure Statement, the applicants brought to the Examiner's attention prior art cited during prosecution of parent patent application Serial No. 08/964,328.

48. In a January 24, 2001 Office Action, the Examiner rejected claims 12, 18 and 19 as being indefinite based on the reference in the claims to a trademark/trade name.

49. With respect to prior art, the Examiner rejected claim 1 under 35 U.S.C. §103(a) as being unpatentable over McAinsh et al. (U.S. Patent No. 4,138,475) in view of Wong et al. (U.S. Patent No. 5,552,429). The Examiner took the position that:

> McAinsh et al. shows a hard gelatin capsule comprised of spheroids coated with a mixture of ethylcellulose and hydroxypropylmethylcellulose. The active agent propranolol is blended with microcrystalline cellulose to formulate the core spheroid. See Abstract, example and claim 1. The reference does not show venlafaxine. Wong el al is relied on for teaching extended release dosage forms comprised of the same ingredients a McAinsh et al including the drugs venlafaxine and propranolol. See column 4, lines 7-10, column 6, lines 54-55, column 7, lines 18-22, formulation 5. To use the venlafaxine of Wong et al in the McAinsh et al capsule with a reasonable expectation of success would have been obvious to one of ordinary skill in the art. Given the teachings of the prior art it would be reasonable to expect that propranolol common to both McAinsh et al and Wong et al could be combined with venlafaxine in a sustained release dosage form to increase patient compliance when the need arises to administer both drugs. The motivation being a desire to obtain optimum drug efficacy over a prolonged period of time while reducing the total number of dosages required.

January 4, 2001 Official Action at pages 3 and 4.

50. The Examiner indicated that claims 21 and 22 are allowed and that claims 2-11, 13-17 and 20 would be allowable if rewritten in independent form.

51. In a February 16, 2001 telephone interview between the Examiner and the applicants' representative, an agreement was reached with respect to all pending claims. During the course of the interview, the Examiner indicated that "[d]iscussed canceling claim one to overcome art rejection and amending claims 12, 18 and 19 to overcome 112 rejection. The examiner would consider claims 21 and 22, amended to delete encapsulated, for allowability pending further search. An amendment will follow."

52. In a February 16, 2001 Request for Reconsideration, the applicants canceled claim 1, amended claims 2, 3, 4, 6, 8, 11, 12-16 and added new claims 23-26. In accordance with the prior Office Action, the applicants' amendments placed the pending claims in condition for allowance.

53. In a February 18, 2001 Communication, the applicants filed a Petition to add Steven A. White as a named inventor.

54. In a May 9, 2001 Notice of Allowability, the Examiner allowed claims 2-26 in response to the amendment filed February 16, 2001.

55. The '171 patent formally issued on August 14, 2001.

B. PROSECUTION HISTORY OF U.S. PATENT NO. 6,403,120 (THE '120 PATENT

1. PROSECUTION HISTORY OF CONTINUATION APPLICATION SERIAL NO. 09/884,412

56. Application Serial No. 09/884,412 was filed on June 19, 2001 as a divisional application of parent application Serial No. 09/488,629, naming Sherman et

al. as joint inventors. The application was filed with the 22 original claims from the '171 patent application and included the same representation with respect to statistically significant improved results of venlafaxine ER over conventional venlafaxine hydrochloride tablets in two 8-week and one 12-week clinical studies.

57. In a June 19, 2001 Preliminary Amendment, the specification was amended to modify the related application information. Original claims 2-22 were canceled and new claims 23-24 were added.

58. In a June 19, 2001 Information Disclosure Statement, the applicants brought to the Examiner's attention the prior art cited in application Serial No. 09/488,620 (sic), which matured into the '171 patent.

59. Application Serial No. 09/884,412 ultimately matured into the '958 patent and the remainder of the prosecution history is described below in conjunction with the description of the '958 patent prosecution history.

2. PROSECUTION HISTORY OF APPLICATION SERIAL NO. 09/950,965

60. On September 12, 2001, well before any office action was issued in parent application Serial No. 09/884,412, Application Serial No. 09/950,965 was filed as a continuation of application Serial No. 09/884,412, naming Sherman et al. as joint inventors. The application was with the 22 original claims described above with respect to application Serial No. 09/488,629, which matured into the '171 patent. The '120 specification, like the above-described parent applications, included the representation that "Venlafaxine ER shows statistically significant improvement over

conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." Original application specification at page 4.

61. In a September 12, 2001 Information Disclosure Statement, the applicants referred the Examiner to the previously cited prior art in parent application 09/488,620 (sic).

62. In a September 12, 2001 Preliminary Amendment, the applicants amended the first page of the application to modify the reference to related patent applications. Additionally, the applicants canceled claims 2-22 and added new claims 23-34, directed, *inter alia*, to a "method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis, which comprises administering orally to a patient in need thereof, an extend release formulation that provides peak blood plasma levels of venlafaxine of no more than about 150ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient." Application claim 23.

63. In a December 5, 2001 Office Action, the Examiner objected to claims 24-34 under 37 C.F.R. §1.75(c) as being improper dependent claims for failing to further limit the subject matter of a previous claim. The Examiner took the position that the claims are dependent claims that depend on a method, however claims 24 and 25 depend upon claim 1 which is a product/composition claim.

64. The Examiner rejected claim 1 under 35 U.S.C. §103 as being unpatentable over McAinsh (U.S. Patent No. 4,138,475) in view of Wong (U.S. Patent No. 5,552,429). The Examiner took the position that:

> McAinsh et al shows a hard gelatin capsule comprised of spheroids coated with a mixture of ethylcellulose and hydroxypropylmethylcellulose.

> The active agent propranolol is blended with microcrystalline cellulose to formulate the core spheroid. See Abstract, example and claim 1. The reference does not show venlafaxine. Wong et al is relied on for teaching extended release dosage forms comprised of the same ingredients as McAinsh et al including the drugs venlafaxine and propranolol. See column 4, lines 7-10, column 6, lines 54-55, column 7, lines 18-22, formulation 5. To use the venlafaxine of Wong et al in the McAinsh et al capsule with a reasonable expectation of success would have been obvious to one of ordinary skill in the art. It would be reasonable to expect that propranolol common to both McAinsh et al and Wong et al could be combined with venlafaxine in the McAinsh sustained release dosage form to increase patient compliance when the need arises to administer both drugs. The motivation being a desire to obtain optimum drug efficacy over a prolonged period of time while reducing the total number of dosages required. It is also reasonable to expect that one may choose to use the same sustained release formulation for either drug alone in a single dosage form for those times when only venlafaxine or propranolol is required to be administered as a sustained/extended release formulation. The goal being to obtain optimum release profiles.

December 5, 2001 Office Action at pages 3 and 4.

65. The Examiner allowed claim 23.

66. In a March 5, 2002 Amendment, the applicants cancelled claim 1, amended claims 24 and 25 and added new claims 35 and 36. The applicants indicated that new claims 35 and 36 were added to more fully claim subject matter of the claimed invention and that amended claims 24 and 25 addressed the Examiner's objection to these dependent claims.

67. In a June 19, 2002 Notice of Allowability, the Examiner allowed claims 23-36 in view of the applicants' March 5, 2002 Amendment.

68. The '120 patent formally issued on June 11, 2002.

3. PROSECUTION HISTORY OF U.S. PATENT NO. 6,419,958 (THE '958 PATENT)

69. The '958 patent was filed on June 19, 2001 as application Serial No. 09/884,412, as a divisional of application Serial No. 09/488,629 (which matured into

the '171 patent) naming Sherman et al. as joint inventors. The '958 patent included the 22 original claims from the '171 patent application and included the same representation with respect to statistically significant improved results of venlafaxine ER over conventional venlafaxine hydrochloride tablets in two 8-week and one 12-week clinical studies.

70. In a June 19, 2001 Preliminary Amendment, the specification was amended to modify the related application information. Original claims 2-22 were canceled and new claims 23-24 were added.

71. In a June 19, 2001 Information Disclosure Statement, the applicants brought to the Examiner's attention the prior art cited in application Serial No. 09/488,620 (sic), which matured into the '171 patent.

72. In a January 14, 2002 Office Action, the Examiner rejected claims 23 and 24 on obviousness-type double patenting grounds based on claims 20 and 21 of the '171 patent.

73. With respect to prior art, the Examiner rejected claim 1 under 35 U.S.C. §103 as being unpatentable over McAinsh (U.S. Patent No. 4,138,475) in view of Wong et al. (U.S. Patent No. 5,552,429). The Examiner took the position that:

> McAinsh et al shows a hard gelatin capsule comprised of spheroids coated with a mixture of ethylcellulose and hydroxypropylmethylcellulose. The active agent propranolol is blended with microcrystalline cellulose to form a core spheroid. See Abstract, example and claim 1. The sustained release results from the coating applied to the individual spheroids. The reference does not show venlafaxine. Wong et al is relied on for teaching extended release dosage forms comprised of the same ingredients as McAinsh et al including the drugs venlafaxine and propranolol. See column 4, lines 7-10, column 6, lines 54-55, column 7, lines 18-22, formulation 5. To use the venlafaxine of Wong et al in the McAinsh et al capsule, coated for sustained release, with a reasonable expectation of success would have been obvious to one of ordinary skill in the art. It

> would be reasonable to expect that propranolol common to both McAinsh et al and Wong et al could be combined with venlafaxine in a sustained release dosage form to increase patient compliance when the need arises to administer both drugs. The resulting combination dosage form would provide optimum drug efficacy over a prolonged period of time while reducing the total number of dosages required.

January 14, 2002 Office Action at page 3.

74. In a April 15, 2002 Amendment, the applicant canceled claim 1 and added new claims 25-28. The applicants submitted a Terminal Disclaimer to obviate the Examiner's obviousness-type double patenting rejection.

75. In an August 7, 2002 Notice of Allowability, the Examiner allowed claims 23-28 in view of the applicants' April 15, 2002 Amendment and Disclaimer.

76. The '958 patent formally issued July 16, 2002.

IV. DUTY OF DISCLOSURE

77. As foundational testimony for the materiality-related opinions expressed below, I may testify about a patent applicant's duty of disclosure owed to the PTO. Dating back at least as early as 1945, the U.S. Supreme Court mandated that a patent applicant has an "uncompromising duty" to disclose material facts bearing on patentability to ensure that a patent springs from a background free from fraud or inequitable conduct. Later, in the 1950's, the then Court of Customs and Patent Appeals emphasized that, in dealing with the PTO, patent applicants must not regard proceedings as adversarial proceedings, and that it is essential to the existence of the patent system in this country that patent applicants disclose to the Patent Office material information bearing on patentability. In 1977, such preexisting case law was codified by the PTO and identified as original PTO Rule 56. 37 C.F.R. §1.56.

78. Original Rule 56 and Rule 56 as amended in March of 1992 require, *inter alia*, that all persons substantively involved in patent application preparation or prosecution disclose to the PTO "material" prior art or information of which they are aware.

79. Prior art or information is defined in original Rule 56 as being "material," if there is a substantial likelihood that a reasonable patent examiner would consider it important in deciding whether to allow the patent application to issue. The March 1992 revision to Rule 56 defined prior art or information as being material if, *inter alia*, it establishes, either by itself or in combination with other information, a "prima facie case of unpatentability" of at least one patent claim. Thus, to be "material" under original Rule 56 (or as revised in 1992) prior art or information need not necessarily render any claim unpatentable.

80. The Federal Circuit has explained that there are different applicable standards that correspond to different levels of materiality. *Digital Control, Inc. v. Charles Mach. Works*, 77 U.S.P.Q.2d 1823, 1828, 1829 (Fed. Cir. 2006). Further, the Federal Circuit explained that the passage of new Rule 56 in March of 1992 did not replace or supplant the original Rule 56 "reasonable examiner" standard. *Id.* at 1829. Thus, in accordance with original Rule 56, a misstatement or omission is "material" and will trigger the duty of disclosure when a reasonable examiner would have considered the misstatement or omission important in deciding whether to allow the application. Alternatively, materiality may be demonstrated by showing that the omission or misrepresentation is material under other recognized tests for materiality such as the objective "but for" standard, that defines the highest level of materiality. The highest

level of materiality is reached when the misstatement or omission regarding prior art "was so material that the patent should not have issued" had the information been disclosed to the examiner. *Id.* at 1828.

81. Materiality is not limited to prior art but embraces any information where there is a substantial likelihood that a reasonable examiner would consider such information important in deciding whether to allow an application to issue as a patent.

82. In order for an applicant's duty of disclosure to be triggered, it is only necessary for the prior art or information to be material to one patent claim. In assessing "materiality," claim language should be given its "broadest reasonable interpretation" consistent with the specification. See, for example, current Rule 56.

83. The duty of disclosure is owed by each of the applicants, the patent attorney(s) handling the application preparation or prosecution, and any other individuals substantively involved in the preparation or prosecution of a patent application. The duty begins when a patent application is filed and does not end until the patent application issues as a patent.

84. An integral part of the duty of disclosure is a duty of reasonable inquiry. Once an attorney or an applicant or any other individual having a duty to disclose has notice that specific information exists that appears to be material, that person cannot ignore that notice in an effort to avoid his or her duty to disclose. Rather, for example, once sufficient information is presented to an applicant to suggest the existence of specific information the materiality of which may be ascertained with reasonable inquiry, such a reasonable inquiry must be undertaken.

85. There can be no question that a non-cumulative prior art reference is "material" (under either of the two above-identified Rule 56 tests for "materiality"), if a reasonable patent examiner would have rejected a patent claim based on the prior art reference on either "anticipation" grounds under 35 U.S.C. §102, or obviousness grounds under 35 U.S.C. §103.

86. With respect to establishing a prima facie case of obviousness involving chemical compounds having close structural similarity, examiners were trained as set forth in MPEP § 2144.09 (Feb. 2000) that:

> A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (discussed in more detail below) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed below and in MPEP § 2144) for an extensive review of the case law pertaining to obviousness based on close structural similarity of chemical compounds. See also MPEP § 2144.08, paragraph II.A.4.(c).
>
> The cited MPEP § 2144.08 (Feb. 2000) indicates, *inter alia*, that:
>
> In fact, similar properties may normally be presumed when compounds are very close in structure. *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have 'very close' structural similarities and similar utilities, without more a *prima facie* case may be made."). Thus; **evidence of similar properties** or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. *Dillon*, 919 F.2d at 697-98, 16 USPQ2d at 1905; *In re Wilder*, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972) (emphasis added).

87. Accordingly, a reasonable Examiner would find it important to know of "evidence of similar properties" in compounds that are structurally similar to the

claimed invention in determining whether the claimed invention patentably distinguishes over structurally similar compounds.

88. Prior art or information that is inconsistent with or contradicts an argument made to support patentability or that refutes an Examiner's position with respect to unpatentability would be important to a reasonable examiner. Current Rule 56 expressly codifies the notion that information is material if it "refutes or is inconsistent with, a position the applicant takes in 1) opposing an argument of unpatentability relied on by the Office or 2) asserting an argument of patentability."

89. For the reasons set forth below, I expect to testify that, based in part on my experience as a former PTO examiner and relying on Impax's technical experts, material prior art or information was not disclosed to the PTO during the prosecution of the patents-in-suit.[1] In my opinion, relying in part on Impax's technical expert, material information described below was not disclosed to the PTO during the prosecution history of the '171, '120, and '958 patents-in-suit including: 1) information inconsistent with the argument for patentability that "venlafaxine showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies," 2) information regarding Alza's venlafaxine extended release formulation, and 3) information regarding whether the '171 and '120 patents-in-suit named the correct inventors.

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[1] It is noted that the identification of material information not disclosed to the PTO is not intended to be exhaustive. Merely because certain information is not identified herein should not be construed as an indication that, in my opinion, such information is immaterial.

A. INFORMATION INCONSISTENT WITH ARGUMENTS FOR PATENTABILITY REGARDING THE EIGHT AND TWELVE WEEK STUDIES SHOULD HAVE BEEN DISCLOSED TO THE PTO

90. In my opinion, relying in part on Impax's technical expert, the applicants failed to disclose "material" information to the PTO that was inconsistent with the applicants' representation that "venlafaxine showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies" for the reasons set forth below.

91. As set forth above, in my opinion, information which is inconsistent with an argument for patentability would have been important to a reasonable patent examiner. Rule 56 as amended in 1992 defines information as material, if *inter alia*, it "refutes or is inconsistent with, a position the applicant takes in 1) opposing an argument of unpatentability relied on by the Office or 2) asserting an argument of patentability." Arguments for patentability may be presented by an applicant in the body of a patent application specification or in a response to a PTO office action.

92. The '171, '120 and '958 patent specifications contain such arguments for patentability. For example, as indicated above, in the '171, '120 and the '958 patent specifications, the applicants alleged, with respect to venlafaxine ER that:

> [t]he use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. **Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.** Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release

formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

See, for example, the '171 patent at column 2, lines 46-55 (emphasis added).

93. In my opinion, the above-quoted passage repeated in the specifications of each of the patents-in-suit constitutes an argument for patentability with respect to at least any claim that specifies diminished incidences of nausea and emesis as a property of venlafaxine ER. In my view, this argument for patentability at least pertains to, for example, '171 claims 20, 22 and 23, '120 patent claims 1-6 and '958 claims 1, 3 and 4.

94. In my opinion, an examiner confronted with claims that, for example, require diminished incidences of nausea and emesis as a property of venlafaxine hydrochloride ER would have recognized the above-quoted representation to the PTO as an argument for patentability based upon "two eight-week and one 12-week clinical studies" showing improved results over conventional venlafaxine hydrochloride.

95. Examiners have been trained that a greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of claims at issue. See MPEP §716.02(a) quoted below. Thus, information that is inconsistent with a representation of alleged improved results would likewise be an evidentiary factor pertinent to the legal conclusion of obviousness of claims at issue that the examiner should consider prior to making a patentability determination.

96. MPEP §716.02(a) instructs Examiners as to the significance of evidence of unexpected results as follows:

716.02(a) Evidence Must Show Unexpected Results [R-2] - 700 Examination of Applications

716.02(a) Evidence Must Show Unexpected Results [R-2]

>

I. < GREATER THAN EXPECTED RESULTS ARE EVIDENCE OF NONOBVIOUSNESS

"A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). In *Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. This result was persuasive of nonobviousness even though the result was equal to that of one component alone. Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.).

>

II. < SUPERIORITY OF A PROPERTY SHARED WITH THE PRIOR ART IS EVIDENCE OF NONOBVIOUSNESS

Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. "Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987) (Evidence showing that the claimed herbicidal compound was more effective than the closest prior art compound in controlling quackgrass and yellow nutsedge weeds in corn and soybean crops was sufficient to overcome the rejection under 35

U.S.C. 103, even though the specification indicated the claimed compound was an average performer on crops other than corn and soybean.). See also *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (unexpected superior therapeutic activity of claimed compound against anaerobic bacteria was sufficient to rebut *prima facie* obviousness even though there was no evidence that the compound was effective against all bacteria).

>

III. < PRESENCE OF AN UNEXPECTED PROPERTY IS EVIDENCE OF NONOBVIOUSNESS

Presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (rejection of claims to compound structurally similar to the prior art compound was reversed because claimed compound unexpectedly possessed anti-inflammatory properties not possessed by the prior art compound); *Ex parte Thumm*, 132 USPQ 66 (Bd. App. 1961) (Appellant showed that the claimed range of ethylene diamine was effective for the purpose of producing " 'regenerated cellulose consisting substantially entirely of skin' " whereas the prior art warned "this compound has 'practically no effect.' "). The submission of evidence that a new product possesses unexpected properties does not necessarily require a conclusion that the claimed invention is nonobvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979). See the discussion of latent properties and additional advantages in MPEP § 2145.

>

IV. < ABSENCE OF AN EXPECTED PROPERTY IS EVIDENCE OF NONOBVIOUSNESS

Absence of property which a claimed invention would have been expected to possess based on the teachings of the prior art is evidence of unobviousness. *Ex parte Mead Johnson & Co.* 227 USPQ 78 (Bd. Pat. App. & Inter. 1985) (Based on prior art disclosures, claimed compounds would have been expected to possess beta-andrenergic blocking activity; the fact that claimed compounds did not possess such activity was an unexpected result sufficient to establish unobviousness within the meaning of 35 U.S.C. 103.).

MPEP 716.02(a) (August 2006); Also see MPEP 716.02(a) (Feb. 2000).

97. Further, Examiners were trained that evidence of unexpected results to be effective in rebutting a prima facie case of obviousness typically involves a

comparison of the claimed subject matter with the closest prior art. For examiner, MPEP 716.02(e) instructs Examiners as follows:

> **716.02(e) Comparison With Closest Prior Art [R-2]**
>
> An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness. *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). "A comparison of the *claimed* invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference." *In re Merchant*, 575 F.2d 865, 868, 197 USPQ 785, 787 (CCPA 1978) (emphasis in original). Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, *In re Finley*, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. *In re Armstrong*, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential).
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>
> I. < THE CLAIMED INVENTION MAY BE COMPARED WITH PRIOR ART THAT IS CLOSER THAN THAT APPLIED BY THE EXAMINER
>
> Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner. *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961) (Claims to a 13-chloro substituted compound were rejected as obvious over nonchlorinated analogs of the claimed compound. Evidence showing unexpected results for the claimed compound as compared with the 9-, 12-, and 14- chloro derivatives of the compound rebutted the *prima facie* case of obviousness because the compounds compared against were closer to the claimed invention than the prior art relied upon.).
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> >
>
> II. < COMPARISONS WHEN THERE ARE TWO EQUALLY CLOSE PRIOR ART REFERENCES
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> Showing unexpected results over one of two equally close prior art references will not rebut *prima facie* obviousness unless the teachings of the prior art references are sufficiently similar to each other that the testing of one showing unexpected results would provide the same information as to the other. *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984) (Claimed compounds differed from the prior art

either by the presence of a trifluoromethyl group instead of a chloride radical, or by the presence of an unsaturated ester group instead of a saturated ester group. Although applicant compared the claimed invention with the prior art compound containing a chloride radical, the court found this evidence insufficient to rebut the *prima facie* case of obviousness because the evidence did not show relative effectiveness over all compounds of the closest prior art. An applicant does not have to test all the compounds taught by each reference, "[h]owever, where an applicant tests less than all cited compounds, *the test must be sufficient to permit a conclusion respecting the relative effectiveness of applicant's claimed compounds and the compounds of the closest prior art.*" *Id.* (quoting *In re Payne*, 606 F.2d 303, 316, 203 USPQ 245, 256 (CCPA 1979)) (emphasis in original).).

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III. < THE CLAIMED INVENTION MAY BE COMPARED WITH THE CLOSEST SUBJECT MATTER THAT EXISTS IN THE PRIOR ART

Although evidence of unexpected results must compare the claimed invention with the closest prior art, applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art. *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) (Evidence rebutted *prima facie* case by comparing claimed invention with the most relevant prior art. Note that the majority held the Office failed to establish a *prima facie* case of obviousness.); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 "would be requiring comparison of the results of the invention with the results of the invention." 357 F.2d at 422, 148 USPQ at 714.).

MPEP 716.02(e) (August 2006); Also see MPEP 716.02(e) (Feb. 2000).

1. Failure To Disclose Information Inconsistent With Alleged Improvement Over Conventional Venlafaxine Hydrochloride

98. In my opinion, information would be inconsistent with the argument that "Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies," if, for example, such information evidences that the two eight-week and one 12-week

studies a) did not show a statistically significant improvement over conventional venlafaxine hydrochloride and/or b) no comparison was made with respect to conventional venlafaxine hydrochloride.

99. The above-quoted patentability argument alleges that venlafaxine ER showed a statistically significant improvement when compared with conventional venlafaxine hydrochloride tablets. Relying on Impax's technical expert, the two eight-week and one 12-week clinical studies referenced in the patents-in-suit were described in the Wyeth submission to the Food and Drug Administration in MDA20-699 to obtain approval for a venlafaxine hydrochloride ER referred to as EFFEXOR® XR. Specifically, these studies consisted of studies 600B-208-US (study 208), 600B-209-US (study 209), and 600B-367-EU (study 367).

100. Relying on Impax's technical expert, the representation made to the PTO with respect to the improvement over conventional venlafaxine hydrochloride tablets in "two eight-week and one 12-week clinical studies" indicates that direct comparisons were made between venlafaxine extended release and conventional venlafaxine hydrochloride.

101. Relying on Impax's technical expert, a person of ordinary skill in the art would understand this statement concerning the results of two eight-week and one 12-week studies allegedly showing a statistically significant decrease in incidences of nausea and vomiting with venlafaxine ER as compared to venlafaxine IR to mean that each of the three studies showed such a decrease. Relying on Impax's technical expert, if it were actually intended that only when data from the three studies was considered collectively (when pooled) did the data show such a decrease, such data

pooling should have been expressly referenced. Further, relying on Impax's technical expert, the statement suggesting that each of the three studies showed a decrease in nausea and vomiting using venlafaxine ER compared to venlafaxine IR is not an accurate representation because studies 209 and 367 did not compare venlafaxine ER with venlafaxine IR, but only compared venlafaxine ER with a placebo.

2. Studies 209 And 367 Involved Comparisons To A Placebo—Not Conventional Venlafaxine Hydrochloride

102. Relying in part on Impax's technical expert, studies 209 and 367, as of the effective filing date of the '171 patent, did not establish statistically significant improvement in nausea experienced by patients receiving venlafaxine hydrochloride extended release when compared with patients receiving conventional venlafaxine hydrochloride tablets. Studies 209 and 367 did not involve patients who receive conventional venlafaxine hydrochloride tablets. Rather, as indicated above, studies 209 and 367 involved patients who received venlafaxine hydrochloride extended release and a placebo. Relying on Impax's technical expert, in my view, the PTO should have been informed that no direct comparison with conventional venlafaxine hydrochloride tablets was made and any basis for the statement that improved results were obtained.

3. Study 208 Did Not Show A Statistically Significant Improvement

103. Additionally, relying on Impax's technical expert, although study 208 did directly compare patients receiving venlafaxine hydrochloride extended release with patients receiving conventional venlafaxine hydrochloride immediate release tablets,

the data from study 208 did not establish statistically significant improvement with respect to level of nausea and incidence of emesis.

104. As indicated above, the '171, '120 and the '958 patent specifications, the applicants alleged, with respect to venlafaxine ER that:

> **....Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. ...**

See, for example, the '171 patent at column 2, lines 46-55 (emphasis added).

105. Additionally, an article by Cunningham, "Once-daily Venlafaxine Extended Release (XR) And Venlafaxine Immediate Release (IR) In Outpatients With Major Depression," Vol. 9, No. 3, Annals of Clinical Psychiatry, 1997, indicated that "[t]he most common adverse event was nausea in 43 (45%) venlafaxine IR-treated, 44 (45%) venlafaxine XR-treated and 10 (10%) placebo treated patients."

106. Relying on Impax's technical expert, this Cunningham article specifically discusses the results from study 208 and evidences that there was no statistically significant improvement evidenced in study 208, when venlafaxine extended release was compared with conventional venlafaxine hydrochloride tablets.

107. Since such information is inconsistent with the argument for patentability proffered in the specifications of the patents-in-suit, such information is material and should have been disclosed to the PTO.

108. The PTO has no in-house testing facilities. Accordingly, an Examiner must presume that representations made with respect to clinical study data, such as set forth in column 2 of the '171 patent, are accurate. Examiners rely on applicants

complying with their duty of disclosure and presenting accurate information with respect to test results.

109. In my opinion, any information indicating that experimental data from the cited studies does not establish that the claimed invention achieved the results set forth in the specification, would have been important to a reasonable examiner.

B. MATERIAL INFORMATION REGARDING ALZA PRIOR ART WAS NOT DISCLOSED TO THE PTO

110. In my opinion, relying on Impax's technical expert, material information regarding Alza's venlafaxine extended release formulation was not disclosed to the PTO.

111. As set forth above, a non-cumulative prior art reference is "material," if, for example, a reasonable patent examiner would have rejected a patent claim based on the reference on either "anticipation" grounds under 35 U.S.C. § 102, or obviousness grounds under 35 U.S.C. § 103. Further, as set forth above, Examiners are required to give claim language its broadest reasonable interpretation consistent with the specification. Thus, in assessing "materiality," claim language should be given its "broadest reasonable interpretation" consistent with the specification. See, for example, current Rule 56. I understand that Wyeth has maintained that the term "extended release formulation" in the patents in suit covers not just the specific formulation containing the particular ingredients described in the specification and used in Wyeth's Effexor XR product, but also any other formulation that releases the active ingredient slower than an immediate-release formulation. For the purposes of the following analysis, I have assumed *arguendo* that Wyeth's proposed interpretation is encompassed by the broadest reasonable interpretation.

112. In my view, relying on Impax's technical expert, a reasonable patent examiner would have rejected at least one claim in each of the patents-in-suit at least under 35 U.S.C. § 102(g) as being anticipated by Alza's prior art venlafaxine extended release formulation

113. Relying on Impax's technical expert, Alza venlafaxine extended release formulation was the subject of clinical study No. 600B-134-US (the 134 study) that was conducted during January to February of 1994 time frame. See Wyeth 022-0017711.

114. In my view, the work of Alza appears to qualify as prior art with respect to at least the claims identified below at least under 35 U.S.C. §102(g) as the prior work of another that was not abandoned, suppressed or concealed.

1. Peak Blood Plasma And Nausea Information Regarding Alza Venlafaxine ER Is Not Merely Cumulative To The Alza PCT Published Application

115. In my opinion, relying on Impax's technical expert, undisclosed information regarding the properties of the Alza Venlafaxine extended release prior work is material and should have been disclosed to the PTO. Information regarding the prior work of Alza would not have important to a reasonable examiner, if such work was merely cumulative to information of record before the PTO. Relying on Impax's technical expert, only limited information about Alza prior art formulations was disclosed to the PTO in Alza's Patent Cooperation Treaty (PCT) application WO 94/27589 (the '589 PCT application). The '589 PCT application, as can be seen from the front page of, for example, the '171 patent was cited to the PTO examiner.

116. Relying on Impax's technical expert, information regarding properties of Alza's venlafaxine extended release formulation highly germane to the claims of the patents-in-suit are not disclosed in the '589 PCT application.

117. The Alza '589 PCT application failed to disclose properties inherent in the Alza prior art formulation that are claimed in the patents-in-suit. For example, the '134 study discloses an Alza venlafaxine extended release formulation that produces a peak blood plasma level in patients in about six hours. See Wyeth 022-001736.

118. In my opinion, relying on Impax's technical expert, a reasonable patent examiner would have rejected various claims in the '171, '120, and '958 patents under at least 35 U.S.C. §102(g) as being anticipated by the prior work of Alza resulting in Alza's venlafaxine extended release formulation.

119. For example, relying on Impax's technical expert, the '134 study evidences that Alza's venlafaxine extended release formulation anticipates, for example, '171 patent claim 25, which defines "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily dosages of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated in extended release formulation that provides a peak blood plasma level of venlafaxine in about six hours, said formulation containing venlafaxine hydrochloride as the active ingredient." Also, see '171 method claims 21 and 24. Also see, for example, '958 patent claim 2.

120. Additionally, the '134 Alza venlafaxine extended release formulation study is also material and would have been important to a reasonable examiner since the study reports a decreased incidence of nausea in patients taking Alza's venlafaxine

extended release formulation as compared to patients taking the conventional formulation. For example, the study indicates that:

> [t]he total frequency of study events was greatest during the treatment period in which subject received the conventional formulation of venlafaxine. For example, nausea, the most common reported study event, occurred in 7 (39%), 2 (11%), and 0 (0%) of the subject who received the venlafaxine conventional formulation, venlafaxine ER, and venlafaxine GITS, respectively.... Thus, the safety results were consistent with the known profile associated with venlafaxine and suggest that the incidence of nausea, a common complaint with the conventional formulation, may be lessened with the use of an extended-release product.

121. Relying on Impax's technical expert, a reasonable examiner would have rejected at least '171 patent, claim 20 under 35 U.S.C. 102 as being anticipated by Alza's venlafaxine extended release formulation. Claim 20 requires providing a therapeutic blood plasma concentration of venlafaxine over a 24-hour period with "diminished incidences of nausea and emesis" and also requires a peak blood plasma level of venlafaxine from about 4 to 8 hours. Also, see '958 patent, claim 1 and the '120 patent, claim 1, which include diminished incidence of nausea and emesis-related limitations.

C. INFORMATION MATERIAL TO WHETHER THE '171 AND '120 PATENTS NAMED THE CORRECT INVENTORS WAS NOT DISCLOSED TO THE PTO

122. In my opinion, information material to whether the '171 and '120 patents named the proper inventors was not disclosed to the PTO for the reasons set forth below.

123. Examiners have been trained that a patent may not be obtained in the name of any inventive entity other than the true inventors. Thus, in order to have a valid patent, a patent must issue in the name of the true and correct inventors.

124. Examiners have been trained that in order for an individual to be properly named as an inventor, it is necessary that the individual contribute to the conception of the invention. The conception must be a complete and operative conception that would enable a person skilled in the art to reduce the conception to practice without further research or exercise of inventive skill. Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.

125. A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed. Two individuals may be joint inventors even though they did not physically work on the invention together or at the same time; and even though each did not make the same type or amount of contribution. An individual need only contribute to the conception of a single claim in a patent to qualify as a joint inventor.

126. Examiners have no way of independently investigating inventorship and must rely on patent applicants representations relating to inventorship. Thus, it would have been important to a reasonable examiner to be apprised of information that suggests that an individual not named as an inventor contributed to the conception of any one claim in an issued patent.

127. The '171 patent includes various claims which expressly recite hydroxypropylmethylcellulose, USP (HPMC) as part of the extended release formulation. For example, claim 1 of the '171 patent defines an "extended release formulation...optionally from about .25% to about 1% by weight of hydroxypropyl-methylcellulose, USP" and claim 12 of the '171 patent defines an "extended release formulation according to claim 1 wherein the spheroids are composed of ...about .5% of hydroxypropylmethylcellulose... ." Also see, for example, claims 4, 6, 8-10 and 19. Also, see '120 patent dependent claims 3, 4, 6 and 12.

128. As indicated in the prosecution history section above, during the prosecution of the '171 patent, in an April 16, 1999 Amendment, the applicants argued that then pending claim 23 was patentable over the applied prior art by arguing, *inter alia*, that:

> [c]anceled Claim 1 is replaced by Claim 23 which is directed to the gravamen of Applicants' invention, namely, the coated spheroids containing venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose for extended release....
>
> Rejection of Claim 1 (new Claim 23) for obviousness
>
> The rejection of Claim 1 under 35 USC 103 for obviousness over McAinsh et al. (US Patent 4,138,475) in view of Wong et al. (US 5,552,429) is respectfully traversed....
>
> Finally, none of the 8 exemplified formulations includes venlafaxine. The two formulations including microcrystalline cellulose, that is, Formulations 4 and 5, include substantial portions of at least one other pharmaceutical excipient-**but not hydroxypropylmethylcellulose.**
>
> For these reasons, the teaching of Wong et al. is deemed not particularly relevant to Applicants' invention of coated spheroids of venlafaxine hydrochloride for extended release.

April 16, 1999 Amendment at pages 6 and 7 (emphasis added).

129. Accordingly, during the prosecution of the '171 patent, the applicants based a patentability argument on the absence of the pharmaceutical excipient, hydroxypropylmethylcellulose (HPMC), from prior art applied by the PTO.

130. Additionally, the significance of utilizing HPMC 2208 was emphasized in the '171 patent specification which stated that the addition of HPMC 2208 to the mix made the production of spheroids practical:

> In the extrusion process, heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids. Addition of hydroxypropylmethylcellulose 2208 to the venlafaxine hydrochloride-microcrystalline cellulose mix made production of spheroids practical.

'171 Patent at column 5, lines 8-13.

131. During the August 3, 2007 deposition of named co-inventor, Deborah Sherman, Ms. Sherman testified that HPMC was added to the formulation that she was working with because she was "having trouble producing appropriate extrudate" using the formulation she had developed. See Sherman deposition transcript at page 96, lines 14-21.

132. Ms. Sherman testified that she was having difficulties coming up with an appropriate extrudate with Wyeth's lab scale extruder using the formulation she had developed. She sought assistance in solving this problem from an individual working for Dow Chemical Corporation. See the Sherman transcript, page 98, lines 6-25.

133. Ms. Sherman identified the Dow representative as Paul Sheskey. Sherman deposition transcript, page 104 at lines 11-13. Ms. Sherman testified that Mr. Sheskey suggested adding a low viscosity grade hydroxypropylmethylcellulose to the formulation she had developed in order to overcome the difficulty with the extruder. *Id.* at page 99, lines 1-13. Ms. Sherman testified that the suggestion to HPMC 2208

originated with Mr. Sheskey. *Id.* at page 105. The conversation with Mr. Sheskey took place in the February 4 to February 6, 1992 time frame. *Id.* at page 111. At her deposition, relying on her lab notebook, Ms Sherman identified experiments using HPMC run on February 13, 1992, that were successful in making acceptable spheroids. *Id.* at page 110, lines 14-24. Ms. Sherman did not identify any successful experiments prior to February 13, 1992.

134. In my opinion, it would have been important to a reasonable examiner to have been informed that an individual, not named as an inventor, provided the suggestion to use HPMC 2208, the excipient that was characterized in the '171 specification as making the "production of spheroids practical."

135. In my opinion, such information regarding Mr. Sheskey's suggestion of using HPMC, which was expressly claimed in the '171 and '120 patents, should have been disclosed to the PTO during the pendency of the '171 and '120 patents so the examiner could have evaluated whether Mr. Sheskey should have been named as a joint inventor.

V. OTHER TESTIMONY

136. To the extent that discovery is not yet complete, it may become necessary to refine and supplement my opinions. My opinions may also require supplementation in view of any other additional information that may come to light, such as during any future deposition of an Alza representative, or in view of any further expert reports from plaintiffs. I may also testify about matters: (1) raised on direct or cross-examination at trial; (2) necessary to rebut any other matters that the Court allows the plaintiffs to introduce or rely upon; or (3) otherwise raised at trial by counsel

or the Court in relation to matters set forth herein. In addition to the items identified above, my testimony may also be based, in part, upon the trial testimony of fact witnesses and other expert witnesses.

VI. DOCUMENTS AND INFORMATION CONSIDERED

137. In formulating the opinions expressed above, I have received, reviewed and/or relied upon the following documents:

Complaint, First Amended Answer & Counterclaims, Reply to Counterclaims

Binder of studies & articles discussed in the inequitable-conduct counterclaim in Impax' Second Amended Answer (via DEP letter):

GMR 24775 re Protocol 600B-134-US (WYETH 022-001711-799)

GMR 26141 re Protocol 600B-136-US (WYETH 004-003274-354)

GMR 26760 re Protocol 600B-143-UK (WYETH 004-003916-984)

GMR 26165 re Protocol 600B-208-US (WYETH 004-013231-374)

GMR 27258 re Protocol 600B-209-US (WYETH 004-014374-497)

GMR 25782 re Protocol 600B-367-EU (WYETH 004-015397-792

File histories for 6,403,120; 6,419,958; and 6,274,171

Integrated Summary of Safety (WYETH 004-019321-542)

Presentation re 1997 Effexor Positioning (WYETH 126-10855-942)

File histories for 6,274,171, Serial No. 60/014,006; Serial No. 08/821,137; and 6,419,948

8/3/07 Deborah Sherman deposition transcript

Alaburda deposition transcript.

VII. COMPENSATION

138. I am being compensated at $580 per hour for my time spent on this case. My compensation is in no way based upon the outcome of this litigation.

VIII. LISTING OF OTHER CASES IN WHICH TESTIMONY HAS BEEN GIVEN AS EXPERT

139. The following is a listing of all presently known cases in which I have appeared as an expert, either at trial or by deposition during approximately the last four years:

1. Powerquest v. Quarterdeck et al. (D. Ct. Utah, Central Division) - April 2003
2. Translogic v. Hitachi (D. Ct. Oregon) - Oct. 2003
3. V.P. Intellectual Prop. L.L.C. v. Nobel Biocare U.S.A. et al. (D. Ct. N.J.) - Sept. 2003
4. Proctor & Gamble v. Coca Cola (D. Ct., Southern District, Ohio) - Dec. 2003
5. Abbott Laboratories et al. v. Baxter Pharmaceuticals Products, Inc. et al. (N.D. Ill. Eastern Div.) - Feb. 2004
6. Pinpoint v. Amazon.com et al. (N. D. Ill. Eastern Div.) - July 2004
7. Virginia State Bar v. Lynt (Cir. Ct. Alex.) - Sept. 2004
8. Bosch v. TRW et al. (D. Ct. Ariz.) - Sept. 2004
9. Metrologic Instruments, Inc. v. PSC. (D. Ct. N. J.) - Nov. 2004
10. Software AG v. BEA Systems, Inc. (D. Ct. Del.) – Dec. 2004
11. Rosemarie Ryan-House et a. v. GlaxoSmithKline PLC, et al (E.D. Va.), Dec. 2004
12. Roche Diagnostics Corp. et al. v. Home Diagnostics et al. (S. D. Ind. March 2005).
13. Network Appliance, Inc. v. BlueArc Corporation (N.D. Cal.) - April 2005

14. In re Certain Digital Processors And Digital Processing Systems, Components Thereof And Products Containing Same (United States International Trade Commission) - Biax Corp., patentee, Texas Instruments, Inc. accused infringer – July 2005.

15. Takeda Chemical Industries et al v. Mylan Laboratories et al. (S.D. N. Y.), September 2005.

16. Nilssen et al. v. Osram et al. (N.D. Ill. E.D.), Nov. 2005, Feb. 2006.

17. One World Tech. et al. v. Rexon Industrial Corp. et al. (N.D. Ill. E.D.), Dec. 2005.

18. Hynix Semiconductor et al. v. Rambus (N.D. Cal.), Jan. 2006.

19. CollegeNet, Inc. v. XAP Corporation (D.Ct. Oregon), March 2006.

20. Vertique, Inc. v. Darby Automation (D.Ct. Fla., Orlando Div.), April 2006.

21. Caterpillar Inc. v. International Truck & Engine Corp. et al. (D. Ct. South Carolina), July 2006.

22. In re Certain Digital Processors And Digital Processing Systems, Components Thereof And Products Containing Same (United States International Trade Commission) - Biax Corp., patentee, Philips, Inc. accused infringer –August 2006.

23. Andrx Pharmaceuticals, LLC v. Glaxosmithkline, PLC et al. (D. Ct. N.D. Florida), December 2006.

24. In re Certain Mobile Telephone Handsets, Wireless Communication Devices and Components Thereof (United States International Trade Commission) - Investigation No. 337-TA- 578; Qualcomm Corp., patentee, Nokia accused infringer –deposition January 2007.

25. Asyst Technologies, Inc. v. Jenoptik et al, (D. Ct. N. D. Cal.), C98 2540 (JF), trial January 2007.

26. Biax v. Intel Corp. and Analog Devices, Inc. (E.D. Texas, Marshall Div.) Civil Action No. 02-05CV-184-TJW., May 2007.

27. Netflix, Inc. v. Blockbuster, Inc. (D. Ct. N. D. Cal.), Case No. C 06 2361, June 2007 deposition.

28. Trimble Navigation Ltd. v. RHS, et al. (D. Ct. N. D. Cal.), Case No. CV 03-01604 PJH, June 2007 deposition.

29. The Regents Of The University of California v. Micro-Therapeutics, Inc. et al. (D. Ct. N. D. Cal.), Case No. CV C 03 05669 JW (RS), July 2007 deposition

30. Connectics Corp. et al. v. Agis Industries et al., (U.S. D. Ct. N. J.), Case No. 05 Civ. 5038 (HAA), Aug. 2007 deposition.

Respectfully submitted,

Date: 9/26/07

Mark E. Nusbaum

Mark E. Nusbaum
Nixon & Vanderhye PC
901 N. Glebe Road -- 11th Floor
Arlington, Virginia 22203

TAB 1

Curriculum Vitae of Mark E. Nusbaum

MARK E. NUSBAUM was born in Washington, D.C. on April 3, 1947 and was admitted to the Virginia bar in 1975. He has been a member of the law firm of Nixon and Vanderhye since July 10, 1986. He specializes in all phases of prosecution of patent applications before the U.S. Patent and Trademark Office in the electronic and computer related art areas. He has served as an expert witness on Patent and Trademark Office practice in many patent infringement litigations.

Mr. Nusbaum served as a member of the U.S. Patent and Trademark Office's Board of Patent Appeals and Interferences from July of 1983 through July 1986 acting in a judicial capacity reviewing adverse decisions of examiners in applications for patents. A decision of the Board constitutes a final agency action and is directly appealable to either the United States Court of Appeals for the Federal Circuit, or the United States District Court for the District of Columbia.

Between November 1980 and July 1983, Mr. Nusbaum served as head of patent examining Art Unit 236 that was responsible for the examination of patent applications in the highly complex data processing system art area. His examining art unit handled patent applications covering computer system architecture and a wide range of systems including a computer, e.g., control systems, communication systems, video game systems, navigation systems, etc.

From July 1969 to November 1980, Mr. Nusbaum served as a patent examiner in the highly complex general and special purpose digital data processing systems arts. He examined patent applications relating to a wide variety of general and special purpose computer systems. The invention claimed in these applications may have, for example, primarily involved a multiprocessor system or any one of the subsystems in a computer system such as the memory subsystem. He achieved a Master's Level rating in this art in 1974 which recognized that this technology for which he was responsible required at least a graduate level degree to understand and that Mr. Nusbaum has mastered this art. Mr. Nusbaum was awarded Full Signatory Authority in 1975 granting him permanent authority to independently finally reject applications or to allow applications to mature into patents. He achieved a Senior Examiner rating in this art in October 1977.

During this time period, Mr. Nusbaum actively participated in the development and clarification of the state of the law regarding the eligibility of computer programs for patent protection. He worked with the Patent and Trademark Office's Solicitor's Office and the U.S. Justice Department in preparing landmark computer program related cases for hearing before the U.S. Supreme Court. In this regard, he served as a technical advisor to the PTO's Solicitor's Office and the U.S. Justice Department in the landmark computer cases, Diamond v. Bradley, Diamond v. Diehr, and In re Chatfield. He participated in drafting the government briefs in Bradley and Diehr.

He served as Chairman of the Patent and Trademark Office's Computer Programming Guidelines Committee, established in 1981 to generate guidelines regarding the eligibility for patent protection of computer programming and mathematical algorithm related inventions. Mr. Nusbaum was the principal author of these guidelines which were incorporated into the Manual of Patent Examining Procedure.

During his career at the U.S. Patent and Trademark Office, Mr. Nusbaum served as a lecturer and instructor on a variety of patent law related topics. Mr. Nusbaum served as a featured speaker during numerous software protection symposiums and during other patent law related programs including those listed below.

1) October 15, 1981 - Computer Law Association, Examination of Computer Software Related Patent Applications

2) February 27, 28 1982 - Oregon and Washington State Patent Law Associations, 35 USC 101 and 35 USC 112, first paragraph issues in computer software related patent applications

3) March 8, 1982 - Commission on Software Use in the 80's, Patent law overview, patent protection for computer software related inventions

4) November 16, 1982 and Dec 3, 1982 - Legal Times' Washington, D. C. and San Francisco Symposiums on Software Protection

5) January 13, 1983 - Annandale High School Business Law class, U.S. Patent System

6) June 1983, Virginia Bar Patent, Trademark, & Copyright Section, Examination

of Computer Related Applications

7) April 1985, Boston Patent Law Association, Computer Related Inventions

Mr. Nusbaum has lectured in Tokyo, Japan on the eligibility of computer programs for the 100th Anniversary Symposium of the Japanese Patent system. Mr. Nusbaum has also served on numerous occasions as the instructor at the Patent Examiner Initial Training course and has served as a lecturer at the Patent Academy. Additionally, during 1981 and 1982, he served as an instructor at the PTO in-house training courses, "Introduction to Computers" and "Designing with Microprocessors".

Mr. Nusbaum's publications include: "Comment, 35 USC 101 Claim Analysis – The Point of Novelty Approach", 62 JPOS 521 (1980) - cited by Justice Stevens in his dissent in Diamond v. Diehr, 209 USPQ at 15, 19; "Comment, Synopsis of In re Bradley", 61 JPOS 745 (1979); Principal Author, "PTO Guidelines on Computer Inventions", PTCJ, October 1981.

Mr. Nusbaum received numerous awards and citations throughout his career at the U.S. Patent and Trademark Office. He received five Special Achievement Awards for the six month periods ending October 2, 1971; March 31, 1973; June 30, 1974; March 27, 1976 and July 1, 1978. Mr. Nusbaum received an Outstanding Performance Rating for Calendar Year 1976 and fiscal years 1978, 1979, and 1980. Mr. Nusbaum received a quality step salary increase for fiscal year 1979. Additionally, Mr. Nusbaum received the United States Department of Commerce Silver Medal Award for his accomplishments as a Patent Examiner between July 1969 and April 1979. Additionally, he received merit pay cash awards in 1981 and 1982.

Mr. Nusbaum received a Bachelor of Science Degree in Electrical Engineering with honors from the University of Maryland in 1969. He was admitted to Tau Beta Pi and Eta Kappa Nu, the National Engineering and Electrical Engineering Honor Societies. In 1974, he received a Juris Doctor Degree from American University's Washington College of Law.

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CHAMBERS OF
SUE L. ROBINSON
CHIEF JUDGE

LOCKBOX 31
844 KING STREET
U.S.COURTHOUSE
WILMINGTON, DELAWARE 19801

Guidelines: Legal Expert Testimony in Patent Cases

In all patent jury trials, the court shows the video "An Introduction to the Patent System" to the jurors in connection with its preliminary jury instructions. The 18 minute video is distributed by the Federal Judicial Center and provides jurors with an overview of patent rights in the United States, patent office procedure and the contents of a patent. Thus, expert testimony from attorneys regarding patent practice and procedure is not required and will not be permitted except in the case of extraordinary circumstances.

"Expert" legal testimony (as opposed to technical testimony) on such substantive issues as invalidity (by anticipation, obviousness, on-sale bar, prior conception, etc.) and claim construction and infringement, generally is not admitted, as descriptions of the law and instructions on the law are matters for the court.

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ONDEO NALCO COMPANY, a Delaware Corporation,	)	
Plaintiff,	)	
v.	)	Civil Action No. 01-537-SLR
EKA CHEMICALS, INC., a Delaware Corporation,	)	
Defendant.	)	

Robert W. Whetzel, Esquire and Steven J. Fineman, Esquire of Richards, Layton & Finger, P.A., Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Michael Dockterman, Esquire, John S. Letchinger, Esquire, Heather A. Boice, Esquire and Jonathan A. Harris, Esquire of Wildman, Harrold, Allen & Dixon, Chicago, Illinois.

Josy W. Ingersoll, Esquire of Young, Conaway, Stargatt & Taylor, L.P., Wilmington, Delaware. Counsel for Eka. Of Counsel: Richard L. DeLucia, Esquire and Michael D. Loughnane, Esquire of Kenyon & Kenyon, New York, New York.

MEMORANDUM OPINION

Dated: March 21, 2003
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On August 10, 2001, plaintiff ONDEO Nalco Company ("Nalco") filed this action against defendant Eka Chemicals, Inc. ("Eka") seeking a declaratory judgment that its 8692 product does not infringe U.S. Patent Nos. 4,385,961 ("the '961 patent"), 4,388,150 ("the '150 patent"), or 5,603,805 ("the '805 patent"), owned by Eka. (D.I. 1) On October 5, 2001, Eka answered and counterclaimed with allegations of infringement and willful infringement of the '150 and '805 patents. (D.I. 15) Nalco subsequently answered Eka's counterclaims and asserted a number of affirmative defenses. (D.I. 81) This court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a).

Presently before the court are various motions. For the reasons that follow: Nalco's motion for ruling on claim construction (D.I. 161) is denied as moot; Eka's motion for partial summary judgment of infringement (D.I. 166) is granted; Eka's motion for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent (D.I. 154) is denied; Eka's motion to strike Nalco's patent law expert's report (D.I. 141) is granted; Eka's motion for summary judgment of no inequitable conduct (D.I. 157) is denied; and Nalco's motion for summary judgment (D.I. 162) is granted in part and denied in part.

II. BACKGROUND

A. The Parties

Eka is a Delaware corporation and the assignee of the '961 patent entitled "Papermaking." Eka is also the assignee of the '150 and '805 patents entitled "Papermaking and Products Made Thereby" and "Silica Sols and Use of the Sols," respectively. Utilizing the technologies of the '961, '150, and '805 patents, Eka has developed papermaking systems and manufactures and sells chemicals used in the papermaking process.

Nalco is a Delaware corporation that also manufactures chemicals for use in the papermaking industry. One of the products Nalco manufactures is its 8692 product, the accused product. This product has been offered for sale in the United States since 1998.

B. The Technologies

The technologies at issue in this case relate to processes of papermaking and the chemicals used in this process. The '805 patent is directed to silica sols and processes using silica sols in the production of paper for improved retention of additives and fines in the paper, as well as improved dewatering in the production process. The '961 and '150 patents are directed to processes of making paper using a binder comprised of cationic starch and colloidal silicic acid, resulting in increased strength and improved levels of retention of additives and fines in the paper.

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted).

If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient

for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. Nalco's Motion for Ruling on Claim Construction

Given the court's claim construction order dated March 21, 2003, Nalco's motion for ruling on claim construction is denied as moot.

B. Eka's Motion for Partial Summary Judgment of Infringement

Eka moves for partial summary judgment that 20 specific sales of Nalco's 8692 product literally infringed claim 3 of the '805 patent. (D.I. 167) Claim 3 is dependent on claim 1 and claims:

> 1. Silica sols having an S-value within the range from 15 to 40 percent comprising anionic silica particles, said silica particles being non-aluminum modified, and having a specific surface area within the range of from 300 to 700 m^2/g.
>
> 3. The silica sols of claim 1 wherein the sol has an S-value within the range of from 15 to 35 percent.

According to the parties, "the only issues in dispute are whether the particles in Nalco's 8692 product are silica particles and, if so, whether the surface area for the silica particles corrected for boron falls within the claimed range when the Nalco 8692 product is sold and/or used." (D.I. 167 at 22)

In its claim construction order, the court construed the term "silica particles" in the '805 patent as "particles of SiO_2, which may include other elements, compounds or substances as well." The term "non-aluminum modified" was construed to mean silica particles that "have not been surface modified with aluminum." Under this construction, Nalco's 8692 product literally infringes the "silica particles" limitation of claim 3 of the '805 patent.

Eka goes on to argue that under the proper surface area measurement techniques, i.e., the Sears method, the surface area of the 8692 product likewise falls within the required range of claim 3. Both parties agree that the surface area measurements must be corrected to account for the presence of boron in the liquid phase of the silica sols in accordance with the Sears method. The parties, however, differ in the amount of correction that must be made. Eka's expert states that a downward correction of 191 m^2/g should be made. (D.I. 168 at A60) Nalco's expert states that the correction should only be 55 m^2/g. (D.I. 169 at A315) Eka argues that even accepting the lower

correction figure offered by Nalco, it is undisputed from Nalco's own surface area and sales data that it sold infringing products on at least 20 occasions. (D.I. 169 at A629)

Nalco does not dispute the surface area data or the sales data for these specific products. The court, after viewing the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion, concludes that the 20 sales identified by Eka were infringing sales; therefore, Eka's motion for summary judgment shall be granted on this issue.

C. Eka's Motion for Summary Judgment That Sales of its BMA-0 Product Do Not Invalidate the '805 Patent

Eka moves for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent, presumably under 35 U.S.C. § 102(b).[1] (D.I. 155) The thrust of Eka's argument is that claim 3 of the '805 patent requires a silica sol with an S-value of 40% or less and Nalco has not shown any evidence that the BMA-0 product sold before 1992 had an S-value in this range.

Reviewing the record submitted, it is undisputed that the BMA-0 product meets all the limitations of claim 3 of the '805 patent other than the S-value range. Eka directs the court to

[1]In its brief, Eka does not argue validity with respect to any specific statutory provision. Since its brief only discusses the sale of its BMA-0 product as non-invalidating, the court assumes Eka is referring to the on-sale bar of § 102(b).

pre-1992 documents which report S-values for the BMA-0 product from 50% to 90%, depending on how the product was made. Nalco relies on a May 1992 document reporting S-values for BMA-0 of 31% and 47%, the former being within the claimed range of 15% to 35%, and asserts that Eka has not produced all relevant documents in this regard.

The court concludes that Eka has failed to carry its burden of proof on this issue. The document relied on by Nalco to show that the BMA-0 product had an S-value of 31% creates a genuine issue of material fact appropriately left for a jury to resolve. The court further concludes that Nalco has failed to demonstrate that Eka's production was so deficient as to warrant a negative inference. As such, Nalco's request that a negative inference be drawn is denied.

D. Eka's Motion to Strike Nalco's Patent Law Expert's Report

Eka moves to strike the expert report of Gerald H. Bjorge, Esquire, on the grounds that it offers legal analysis and opinion which is contrary to this court's standing guidelines on the appropriate scope of patent law expert testimony. (D.I. 142) Eka contends that Mr. Bjorge, a patent attorney, is not a technical expert in the relevant field and cannot provide expert testimony on any aspect of papermaking or papermaking chemistry. In his expert report, Mr. Bjorge "walks through" the file history

of the '805 patent and opines as to how the United States Patent and Trademark Office would have responded had certain prior art been disclosed to it during the prosecution of the '805 patent.

Having reviewed the report, the court concludes that the content exceeds the permissible scope of a patent law expert's testimony. Therefore, the report and testimony based on said report is stricken.

E. Eka's Motion for Summary Judgment of No Inequitable Conduct

Eka moves the court for summary judgment of no inequitable conduct in the procurement of the '805 patent. (D.I. 158) In support of its motion, Eka contends that Nalco never pled the four inequitable conduct claims it raised for the first time in Mr. Bjorge's expert report. Rather, the only inequitable conduct charges in the pleadings are those found in the first amended complaint. Since Nalco chose not to include in its pleadings any of the allegations of inequitable conduct now raised in its expert report, it should be barred from raising these claims at trial.

Nalco argues that it pled the affirmative defense of inequitable conduct in its answer and since Eka failed to seek a more definite statement of the charges until now, it has waived its objection. The proper remedy for insufficient pleading is a Rule 12(f) motion to strike or a Rule 12(e) motion for a more definite statement. Nalco contends that had either of these

motions been made by Eka, the pleading could have been cured.

The court agrees that the proper vehicle for curing pleading deficiencies is by a motion for a more definite statement pursuant to Fed. R. Civ. P. 12(e) or by a motion to strike pursuant to Fed. R. Civ. P. 12(f). See EMC Corp. v. Storage Tech. Corp., 921 F. Supp. 1261 (D. Del. 1996). In the absence of such a motion, the question becomes whether there has been sufficient notice to the opposing party of the specific inequitable conduct allegations to allow for full and fair discovery of such. In this case, certain of the specific allegations of inequitable conduct are contained only in an expert report now stricken from the record, as would the testimony based on said report. Under the circumstances, Eka's motion for summary judgment is granted as to the four theories addressed in the expert report. The motion is denied, however, as to the inequitable conduct allegations properly pled in the amended complaint.

F. Nalco's Motion for Summary Judgment of Non-infringement and Invalidity

1. Non-infringement

Nalco moves for summary judgment that its 8692 product does not infringe any of the patents in suit either literally or under the doctrine of equivalents. (D.I. 163) With respect to the '805 patent, as noted above, the court adopted a broader construction of the "silica particles" and "silica sols"

limitations than that proposed by Nalco. Under the court's construction, Nalco's 8692 product literally infringes these limitations.

Nalco further contends, however, that its 8692 product does not meet the surface area limitations of claim 3 of the '805 patent. In support of its argument, Nalco asserts that at the time of manufacture, the 8692 product particles have a surface area outside the range of the claim limitation. Furthermore, Nalco argues that there is no evidence of record demonstrating that its customers store the 8692 product long enough to cause a drop in surface area to a range falling within the claim limitations. Not surprisingly, Eka disputes this allegation and points to the report of one of its experts concluding that the majority of sales of the 8692 product fall within the range of the surface area limitation of claim 3 of the '805 patent.

Viewing the underlying facts and all reasonable inferences therefrom in the light most favorable to Eka, as it must on summary judgment, the court concludes that there is a genuine issue of material fact as to whether or not the 8692 product, as manufactured or stored, meets the surface area limitations of claim 3 of the '805 patent. Therefore, Nalco's motion is denied as to this issue.

Nalco also argues that its 8692 product does not meet the "papermaking" limitation of the '150 patent because it does not

itself manufacture paper. Additionally, Nalco argues that it does not indirectly infringe the '150 patent by selling the 8692 product to papermakers since there can be no indirect infringement without proof of direct infringement.

Eka refers to Nalco's own 30(b)(6) discovery information as illustrating that Nalco's customers use the 8692 product in an infringing manner and that, viewing the evidence in a light most favorable to Eka, there is sufficient evidence of record to demonstrate a genuine issue of material fact. The court agrees and declines to grant Nalco's motion on this issue.

Nalco finally argues that the court should grant summary judgment of non-infringement of the patents in suit under the doctrine of equivalents because Eka has not supplied any evidence or theory on equivalents and, furthermore, it is barred by the doctrine of prosecution history estoppel from asserting equivalents with respect to the "non-aluminum modified" limitation in the '805 patent.

Upon review of the evidence of record, the court agrees with Nalco that Eka has failed to provide sufficient evidence to support a theory of infringement under the doctrine of equivalents.[2] Therefore, Nalco's motion of summary judgment of non-infringement under the doctrine of equivalents is granted.

---

[2]The court finds an expert's conclusory reference to the phrase "insubstantial difference," without more, is an insufficient doctrine of equivalents analysis.

2. Invalidity

a. Obviousness

Nalco argues that claim 3 of the '805 patent is obvious in light of U.S. Patent No. 2,750,345 ("the '345 patent").[3] (D.I. 163) The '345 patent discloses an S-value of 40% and claim 3 requires an S-value of between 15% and 35%. Nalco asserts that the claimed range and the range disclosed in the prior art are close enough that a person of ordinary skill in the art would expect the silica sols disclosed in the '805 patent to have the same properties as the silica sols disclosed in the '345 patent. As further support of this position, there is record evidence indicating that fluctuations in S-value of 5% or more do not affect the performance of silica sols in the presence of cationic starch.

Eka counters with the assertion that the '345 patent teaches away from having a low S-value and specifically prefers silica particles in which the degree of aggregations is minimal, i.e., a high S-value. In contrast, the '805 patent expressly teaches that a lower S-value is preferred.

The court concludes that upon viewing the facts and evidence in a light most favorable to Eka, entry of a summary judgment on

[3]Nalco argues that claims 1, 2 and 4 are anticipated under 35 U.S.C. § 102(b), however, Eka subsequently stipulated that it would not be asserting claims 1, 2, 4, 6 or 8 against the 8692 product either now or in the future. As such, the court will not address this argument.

the issue of obviousness is not warranted. It is evident that the '345 patent teaches a silica sol with S-values of 40% to 90%, preferably 70% to 90%. ('345 patent, col. 7, ll. 45-50) Furthermore, the '345 patent specifically states that "[i]t is particularly preferred to employ silica sols in which the degree of aggregation is at a minimum" and "[t]he gel content of preferred products is not in excess of an amount equivalent to a percent solids, in the dispersed phase, of 40 per cent..." ('345 patent, col. 3, ll. 45-47; col. 7, ll. 52-55) Both of these statements teach that a higher S-value is preferred. It is equally evident that the '805 patent teaches that silica sols with a high microgel content, i.e., a low S-value of preferably between 15-35%, provide "a substantially improved effect" with respect to retention and dewatering in paper. ('805 patent, col. 1, ll. 51-60)

Given the record, the court finds that there is a genuine issue of material fact as to whether a person of ordinary skill in the art would consider the '805 patent obvious in light of the '345 patent.

b. Enablement

Nalco argues that the '805 patent is invalid for lack of enablement under 35 U.S.C. § 112, ¶ 1. In support of this argument, it provides the expert report of Dr. Robert Pelton. In his report, Dr. Pelton summarily states that in several

experiments done at his request, a colleague was unable to make the silica sols of the '805 invention following the specification.

Eka attacks this argument as inadmissible hearsay since Dr. Pelton apparently did not oversee the experiments and had no idea of how the experiments were done or even if they were done. Furthermore, no experimental data or information regarding the alleged "experiments" was provided so that Eka could test Dr. Pelton's data and opinions.

The court concludes that Dr. Pelton's report regarding enablement is inadequate to support Nalco's enablement defense. Therefore, Nalco's motion is denied in this regard and that part of Dr. Pelton's report and testimony is stricken.

c. Inequitable conduct

Nalco argues that the '805 patent is unenforceable due to Eka's inequitable conduct in procuring the patent. In support of its argument, Nalco relies on a 1996 article authored by two inventors of the '805 patent. As discussed above, however, the allegations of inequitable conduct based on this article were never pled by Nalco and the expert report expounding these theories has been stricken. Therefore, summary judgment of inequitable conduct based on this reference is denied.

V. CONCLUSION

For the reasons stated: Nalco's motion for ruling on claim

construction (D.I. 161) is denied as moot; Eka's motion for partial summary judgment of infringement (D.I. 166) is granted; Eka's motion for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent (D.I. 154) is denied; Eka's motion to strike Nalco's patent law expert's report (D.I. 141) is granted; Eka's motion for summary judgment of no inequitable conduct (D.I. 157) is denied; and Nalco's motion for summary judgment (D.I. 162) is granted in part and denied in part. An appropriate order shall issue.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ONDEO NALCO COMPANY, a Delaware Corporation, Nalco, v. EKA CHEMICALS, INC., a Delaware Corporation, Eka.	)	Civil Action No. 01-537-SLR

O R D E R

At Wilmington, this 21st day of March, 2003, consistent with the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Nalco's motion for ruling on claim construction (D.I. 161) is denied as moot.

2. Eka's motion for partial summary judgment of infringement (D.I. 166) is granted.

3. Eka's motion for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent (D.I. 154) is denied.

4. Eka's motion to strike Nalco's patent law expert's

report (D.I. 141) is granted.

5. Eka's motion for summary judgment of no inequitable conduct (D.I. 157) is denied.

6. Nalco's motion for summary judgment (D.I. 162) is granted in part and denied in part.

Sue L. Robinson
United States District Judge

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

L'OREAL S.A. and COSMAIR, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 98-424-SLR
REVLON CONSUMER PRODUCTS CORP.; CHARLES REVSON, INC.; ALMAY, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 24th day of February, 2000, having reviewed the various motions in limine filed by the parties to the above captioned litigation;

IT IS ORDERED that:

1. **Henlopen "settlement agreement"** (D.I. 317). Plaintiffs move to exclude defendants from introducing any evidence or testimony, or making any argument, concerning L'Oreal's "settlement agreement" with Henlopen Manufacturing Co., Inc. on the grounds that the agreement "was in settlement of a dispute regarding Henlopen's infringement of the French counterpart to the patent in suit" and, therefore, is not admissible to prove the amount of damages that defendants should pay to plaintiffs pursuant to Fed.R.Evid. 408. The court disagrees, as there is no evidence of record demonstrating that the "Henlopen - L'Oreal Agreement," as so captioned, is anything

other than a "license," as so characterized in the very agreement at issue, negotiated in a typical commercial setting where a patentee has notified a competitor of its potential infringement. Such evidence, therefore, is relevant to the determination of a reasonable royalty. With respect to plaintiffs' request that two Revlon documents be admitted with references to the Henlopen agreement redacted, said request is denied as well.

2. **Third party opinions of counsel** (D.I. 320). Plaintiffs move to exclude defendants from introducing before the jury any evidence, testimony or argument regarding third party opinions or statements of counsel on the patent in suit. Defendants have responded that they do not intend to introduce the legal advice received by Henlopen as "factual evidence of invalidity" or as relevant evidence of willfulness. (D.I. 342 at 2) To the extent that plaintiffs seek a broader ruling without identifying any further evidence, the court declines to do more than advise the parties that, before any such evidence is to be introduced through a witness, the offering party must so advise opposing counsel and the court in order to determine the admissibility of such evidence in a focused context.

3. **Revlon opinions of counsel** (D.I. 321). Plaintiffs move to exclude defendants from introducing before the jury any evidence, testimony or arguments regarding opinions rendered by counsel in April 1996 and September 1998 to Revlon on the patent in suit. Based on the discussion in SRI Int'l, Inc. v. Advanced Tech. Labs., Inc., 127 F.3d 1462, 1467-68 (Fed. Cir. 1997), the

court concludes that evidence of legal advice rendered subsequent to the commencement of infringing activity is relevant to the issue of willfulness and should be admitted.

4. **Willfulness-related evidence** (D.I. 323). Defendants move to preclude plaintiffs from offering evidence relating to willful infringement prior to a liability verdict. The motion is denied, as contrary to this court's trial practice.

5. **Patent law expert** (D.I. 325). Defendants move to limit the testimony of plaintiffs' patent law expert to matters of U.S. Patent and Trademark Office practice and procedure. Plaintiffs contend that they do not intend to offer testimony contrary to the court's guidelines, consistent with the motion. The motion, apparently unopposed, is granted. The court notes in this regard, however, that no expert shall be permitted to offer an opinion of law or an opinion as to "the thoroughness of the consideration of those issues" considered by the examiner.

6. **Plaintiffs' expert witness on mascara brush design** (D.I. 326). Defendants move to limit the testimony of John M.B. Ford, offered by plaintiffs as an expert in the field of mascara brush design and manufacture. The motion is granted in part and denied in part. As noted by plaintiffs, Fed.R.Evid. 703 permits a testifying expert to form opinions and draw inferences from any evidence "perceived by or made known to the expert at or before the hearing." Such evidence then is subject to disclosure at trial. The motion is denied, therefore, with respect to any evidence relied upon by Mr. Ford to form those opinions based on

his proven experience and expertise, e.g., as to infringement.[1] The motion is granted, however, with respect to those "opinions" to be offered by Mr. Ford which do not rest upon any experience or expertise claimed by this witness, e.g., the date of invention.

7. Appointment of a neutral interpreter (D.I. 324). Defendants move for appointment of a "neutral" interpreter based on a perceived "personal bias" or "partiality" on the part of the independent, certified court interpreter who has provided interpreting services at ten multi-day depositions of L'Oreal's French speaking witnesses. The court declines on the record presented to preclude the services of said interpreter, Ms. Abreu. In the absence of the parties' agreement as to the retention of one qualified interpreter, the parties shall each hire a qualified interpreter to service their interpretative needs and to serve as a check on the abilities of the opposing parties' interpreter. The court notes in this regard, however, that the trial will be a timed proceeding and any time wasted by the parties' bickering over inconsequential interpretative nuances will be assigned against the offending party.

United States District Judge

[1]The record provided was insufficient for the court to determine at this time whether Mr. Ford in fact has the industry experience to enable him to offer testimony as to the sale and marketing of prior art brushes.

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LUCAS AEROSPACE, LTD.,	:	
Plaintiff and Counter Defendant,	:	
v.	:	Civil Action No. 93-525-JJF
UNISON INDUSTRIES, L.P.,	:	
Defendant and Counter Claimant.	:	

O R D E R

WHEREAS, Defendant Unison Industries, L.P. ("Unison") filed Motion in Limine No. 2 to Limit the Testimony by Plaintiff's Patent Law Expert A. Donald Messenheimer (D.I. 269);

WHEREAS, Unison contends that Mr. Messenheimer as a patent law expert should not be permitted to give opinions on the issues of law or the legal significance of the facts;

WHEREAS, Lucas Aerospace, Ltd. ("Lucas"), by way of response contends that Mr. Messenheimer's testimony will provide the jury and the Court with the benefit of his specialized knowledge regarding the practice of obtaining a patent and the procedures followed in the application which resulted in the patents at issue;

WHEREAS, Lucas further contends that any objections to particular questions are more appropriately raised during the course of trial at the time Mr. Messenheimer's testimony is elicited before the jury;

WHEREAS, the Court finds that Mr. Messenheimer is offered as a witness on practice and procedure in the Patent and Trademark Office as indicated by Lucas in their briefing;

WHEREAS, the Court finds that "patent law experts" are permitted to testify about Patent Office practice and procedure but not to draw inferences or make statements or conclusions about the patent law of the case;

NOW THEREFORE, IT IS HEREBY ORDERED this 9 day of March, 1995, that Unison's Motion in Limine No. 2 to Limit the Testimony by Plaintiff's Patent Law Expert A. Donald Messenheimer is GRANTED, and Mr. Messenheimer is limited to factual recitations concerning practice and procedure in the Patent and Trademark Office.

Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THORN EMI NORTH AMERICA, INC.,	)	
	)	
Plaintiff,	)	Civil Action No.
	)	92-673 (RRM)
v.	)	
	)	
MICRON TECHNOLOGY, INC., and	)	
	)	
Defendants.	)	
	)	
MICRON SEMICONDUCTOR, INC.,	)	
	)	
Counterclaimant,	)	
	)	
v.	)	
	)	
THORN EMI NORTH AMERICA, INC.,	)	
	)	
Counterdefendant.	)	

Federal Courtroom
No. 4 - 2nd Floor
U.S. Courthouse
844 King Street
Wilmington, Delaware

Tuesday, November 23, 1993
1:15 p.m.

BEFORE: HONORABLE RODERICK R. McKELVIE
United States District Court Judge

Pretrial Conference

WILCOX & FETZER
1330 King Street - Wilmington, Delaware 19801
(302) 655-0477

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The other day Judge Niece had to walk through with me some of the other mistakes that she thought were in there, most of them had to do with issues of law versus issues of fact. And I'm going to look through them.

And there may never be a solution in life about this, but I do think what ends up happening is people compromise by building a camel in the instructions and nobody pays much attention to it. And I spend an hour up here reading to the jury stuff that just doesn't make a whole lot of sense, but we will keep working on it and we'll see if we can improve it.

Okay. Expert witness. Let me talk for a minute about patent office practice and procedure on expert witnesses on law. As people know, the other judges in this district and I have adopted a general practice of stating that we don't allow opinions on issues of law, that we do allow parties to call expert witnesses to testify on patent office practice and procedure. And while I know that certain lawyers think that's an exception you can drive a truck through and you can offer all kinds of opinion on law, in any event I try to stop

that truck from passing through this courtroom. And I like to try to be as clear as I can be about what my limitations are so there is no embarrassment during the trial.

And if you put a witness on and he's on and off in three minutes because you don't want to here it, I won't let him talk to the jury about it. I believe witnesses, expert witnesses on patent office practice and procedure tend to be helpful in the sense that you can put them on the stand, they can take the file and they can walk the jury through the file to explain to them what has happened in the patent office and what the context is for what's happening.

And maybe that's helpful in part because the Court's limit discovery and testimony on patent office practice and procedure. For example, we can't have a patent examiner here. So to me it's almost an evidentiary aid to bring an expert in, hand him a document and use a witness on the stand to walk the jury through a paper that's otherwise admitted into evidence, but they may not understand it other than through argument by counsel.

Now testimony on patent office practice and procedure to me means patent office practice and procedure, but not opinions on what I think are questions of law that arise on what the significance may be on certain things that took place at the patent office.

So in connection with Mr. Bjorge, I can tell you that it looks like he's going to be testifying to some things that I wouldn't normally allow an expert to testify to, and I suggest that people look back again at the experts on questions of law and see whether they're going to testify on questions of law or practice and procedure.

Okay. So now I have some spots tabbed in the pretrial order that I'm happy to talk to, but I have a feeling as soon as I open them up things are going to start to degenerate. I will pick some easy ones first.

Procedure for notifying the other side as to who is going to testify, that's an easy one, isn't it? Two parts to that. You all want notice on who is going to testify next, and I don't want dead time. And in the trial we just finished we did have a good bit of dead time; looks like

EXHIBIT G

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

F. HOFFMAN-LA ROCHE, LTD., Plaintiff, v. IGEN INTERNATIONAL, INC., ORGANON TEKNIKA CORPORATION, and ORGANON TEKNIKA B.V., Defendants.	:	Civil Action No. 98-318-JJF

- - -

Wilmington, Delaware
Tuesday, October 24, 2000
9:30 a.m.

- - -

BEFORE: HONORABLE JOSEPH J. FARNAN, JR., U.S.D.C.J.

APPEARANCES:

RICHARD K. HERRMANN, ESQ.
Blank Rome Comisky & McCauley LLP
-and-
DANIEL A. BOEHNEN, ESQ., and
GRANTLAND G. DRUTCHAS, ESQ.
McDonnell Boehnen Hulbert & Berghoff
(Chicago, Illinois)

Counsel for Plaintiff

JACK B. BLUMENFELD, ESQ.,
MARY B. GRAHAM, ESQ.,
MARYELLEN NOREIKA, ESQ.,
KAREN JACOBS LOUDEN, ESQ., and
RICHARD W. ELLIS, ESQ.
Morris, Nichols, Arsht & Tunnell

Counsel for Defendants

MINUSCRIPT WITH WORD INDEX

THE COURT: Give me that number roughly. What would that number be roughly?

MR. BLUMENFELD: I don't know the answer to that. I don't know what the cost number is. I know what the list price is. We can go back and get that information. I think we can work this out.

THE COURT: You have the three categories. If you can't agree, give me the hard numbers on the first two and I will tell you what the kicker is going to be.

MR. BOEHNEN: We have been asked for the cost of goods and haven't been able to get it.

THE COURT: You are going to get it sold. So the application is granted on the principles discussed.

MR. BOEHNEN: Would you direct the defendants to give us their information on the cost of goods sold? We should be getting that for damages anyway.

THE COURT: Yes. He said he is going to do that and I have ordered that.

MR. BLUMENFELD: That information has been provided.

THE COURT: You should be able to get that.

MR. BOEHNEN: Okay, Your Honor. I believe that brings us up to (e) on the next page. The protective order, this is the generic kind of protective order that is normally entered at the outset of a case, both sides have presented

them, and the essential issue I will turn over to Mr. Drutchas. Or maybe you know what your ruling is, have had a chance to read it.

MR. DRUTCHAS: You may be fully aware. Two protective orders, HLR has proposed one that has the same terms for all the parties. The defendants have proposed one that has two tiers for Igen documents, or Igen or HLR documents, and two separate tiers for Organon Teknika documents as to who has access, basically requiring us to be under a protective order that we think isn't equally applied across the board.

THE COURT: It should be a two-tier order. As I understand the presentations, that would work. I don't know what else to tell you.

MR. BOEHNEN: Two tiers equally across the board.

THE COURT: Yes. If you want to have a carveout for something unusual, call me.

MR. BOEHNEN: The next issue, Your Honor, gets into some other expert witnesses. The first one is a patent attorney named John Goolcasian. We submitted his curriculum vitae and they have refused to agree to let him have access under the protective order.

MR. BLUMENFELD: Your Honor, this is a very narrow issue. Mr. Goolcasian is a patent lawyer down in Virginia. And when we got the undertaking, my presumption --

this, by the way, is a Bench trial. This isn't a jury trial. My presumption was that they wanted him --

THE COURT: Patent law expert.

MR. BLUMENFELD: We are the defendant. It is their patent. I said why does he need access to our confidential information? The response I got was, oh, no, he is also going to testify on willfulness. And my understanding of the law on willfulness is that it's the client's state of mind. I don't think Mr. Goolcasian is going to have much to add about the client's state of mind. If Your Honor wants to hear from him, then I guess we can let him see it. When I asked Mr. Boehnen this morning, what is it you want him to see, and he said I want to have him have the ability to see any of the 175,000 pages of documents --

THE COURT: He didn't really say that. You misunderstood him.

MR. BLUMENFELD: It's close enough.

MR. DRUTCHAS: If I can respond, Your Honor. As far as Mr. Goolcasian's testimony goes, there is really two aspects. One, getting to the ultimate trial issue, and whether you want to have his testimony or not is something that we should really be resolving in a motion in limine, not at this stage. We are certainly entitled to have the assistance of an expert such as Mr. Goolcasian assist us with preparing the case and potentially be an expert, assuming

that this Court ultimately --

THE COURT: Not really. If you want assistance in preparing the case, hire him as special litigation counsel. If you want him to come under the rules of an expert witness, you are in a different ballgame. And in this district, when you get into that patent law/expert/et cetera area, we have a very consistent view. And the view is that they are not helpful. And not only do we mostly exclude them on Bench trials, but in jury trials they are so severely limited, I can't figure out why anybody continues to propose them. It's been called the anti-Manbeck, whatever that guy's name is, employment decision, the former Commissioner. But at any given period of time, it started with Chisum, we put him out of here and we have gone through different -- I am trying to be helpful to you in a way that makes you understand -- he didn't really get to see all the information they have because we don't have a place for him in the expert column.

MR. BOEHNEN: Can I ask, what would the Court's view be of an expert witness on the competency of opinion of counsel? Their defense to willfulness is reliance on opinion of counsel. One of the things they have to show is that it is a competent opinion.

MR. DRUTCHAS: Let me add to that, Your Honor. The Federal Circuit, in a case, In Re Hayes, and

EXHIBIT H

238

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORNING INCORPORATED, ARTIFICIAL SENSING INSTRUMENTS ASI AG,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 03-633 JJF
SRU BIOSYSTEMS, et al.,	:	
Defendants..	:	

MEMORANDUM AND ORDER

Pending before the Court is Defendants' Motion To Exclude The Expert Report And Testimony Of Corning And ASI's Patent Law Expert, Gerald J. Mossinghoff (D.I. 129). For the reasons discussed, Defendants' Motion will be granted.

PARTIES' CONTENTIONS

By their motion, Defendants contend that Mr. Mossinghoff's report and proposed testimony, while couched as explanations of Patent and Trademark Office ("PTO") practices and procedures, consist primarily of legal opinions on various patent issues, including ultimate issues of law.

Plaintiffs contend that Mr. Mossinghoff's opinions on PTO procedures are relevant and within the proper scope of expert testimony on patent matters.

DISCUSSION

Because Mr. Mossinghoff's report and proposed testimony deal primarily with internal patent office procedures, the Court will grant Defendants' Motion To Exclude The Expert Report And Testimony Of Corning And ASI's Patent Law Expert, Gerald J. Mossinghoff (D.I. 129).

NOW THEREFORE, IT IS HEREBY ORDERED this 5 day of November 2004, that Defendants' Motion To Exclude The Expert Report And Testimony Of Corning And ASI's Patent Law Expert, Gerald J. Mossinghoff (D.I. 129) is GRANTED.

Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE

EXHIBIT I

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

SOFTWARE AG, and SOFTWARE AG, INC. : Civil Action

Plaintiffs :

V. :

BEA SYSTEMS, INC., :

Defendant : No. 03-739-GMS

- - -

Wilmington, Delaware
Monday, April 4, 2005
10:00 a.m.

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

APPEARANCES:

MARY B. GRAHAM, ESQ.
Morris, Nichols, Arsht & Tunnell
-and-
WILLIAM D. COSTON, ESQ., and
JAMES R. BURDETT, ESQ.
Venable LLP
(Washington, D.C.)

Counsel for Plaintiffs

STEVEN J. BALICK, ESQ.
Ashby & Geddes
-and-
MICHAEL A. JACOBS, ESQ., and
MATTHEW D'AMORE, ESQ.
Morrison & Foerster
(San Francisco, California)

Counsel for Defendant

THE COURT: Good morning. Keep your seats, please. This is an office conference. Big office.

Let's start with a round from plaintiff of introductions.

MS. GRAHAM: Good morning, Your Honor. Mary Graham. With me today are Bill Coston from Venable and Jim Burdett, also from Venable.

THE COURT: Welcome back.

(Counsel respond "Thank you.")

THE COURT: Mr. Balick.

MR. BALICK: Good morning, Your Honor. Michael Jacobs and Matt D'Amore from Morrison & Foerster and Thomas Burke from BEA.

THE COURT: Good morning.

I understand there was a query as to whether we would be here until lunch. We will in all likelihood be here until after lunch, quite frankly. We will break at 12, because I have something to do at 12, and we all need to eat something. We will be here as long as it takes. If that means we have to be overnight, we will be here till the next day. I hope it doesn't mean that. It depends upon the level of acrimony in the room. I say that with tongue partially in cheek. But given the papers I have reviewed over time, I expect the argument to be vigorous, if not detailed.

We will take the time we need to take. What I am going to do is start out with the motions in limine.

What I will attempt to do is to shift back and forth between the parties, in an effort to avoid anyone feeling they are being beat up on exclusively as much as anything else, but seriously, just to have at least what I perceive to be a fair process.

I would like to take, having said that, BEA's Motions 1 through 4 first. I only do that because it seemed to me, and it may not be the case -- and if it comes to pass that as we discuss this I conclude it is not the case, then we will get right on with SAG's first motion -- it seems to me we can probably dispose of 1 through 4 together.

I am going to ask whoever is carrying the laboring oar -- Mr. D'Amore, let me share a thought with you. It seems in 1 through 4, it seems there is a theme you raise of confining -- we know, Rule 26(a)(2)(B) requires expert testimony for that which is revealed in their expert reports. I am assuming that both sides agree with that general proposition, that the rules so require.

Am I miscasting that, Mr. D'Amore?

MR. D'AMORE: Your Honor, I think it's twofold. It is correct that we are saying that the experts should be limited to their expert reports. That goes for both sides. The issues that we raise in Motions 1 through 4 and the

first motion, doctrine of equivalents is a good example, we say it is not quite enough to limit Dr. Ligler to his expert report in this regard, because on the doctrine of equivalents, what is in his expert report isn't sufficient under the Honeywell case, for example.

So while it's fine to say he --

THE COURT: It is not sufficient to even raise an equivalence issue.

MR. D'AMORE: It is not sufficient to even raise an equivalence issue, that's correct. While it is fine to say that he has very little reference to the doctrine of equivalents in his report and he will only testify about what is in his expert report, the fact is he doesn't lay the technical predicate for allowing a doctrine of equivalents case to go to trial on the couple of things he does raise.

Therefore, we say, since it wouldn't be enough to survive a directed verdict, for example, he shouldn't be allowed to testify on it at all and allow it to go to the jury. Again, that was the holding in Honeywell.

To go back to the general principle, it is true that we say, in these cases, the experts should be limited to their report. There are a few cases, like the doctrine of equivalents motion, where if you study the report, we said, and you study his testimony, it doesn't rise to the level of something that should go to the jury.

17

motion is granted, conditioned as just articulated by Mr. D'Amore.

We are going to go shifting back and forth. Let's go to Section No. 1, the so-called patent law expert. I think both parties understand the Court's view of patent law experts. But I think there is still an issue outstanding. Is that correct? Mr. Burdett?

MR. BURDETT: Yes, Your Honor.

There are four basic points that Software AG would like to raise, Your Honor. We don't believe this is the first time that they have been raised.

Clearly, Mr. Nusbaum is being proffered as a Patent Office procedures expert. But in actuality, what his report and much of his testimony was directed to was as a patent law expert, which this Court generally does not like to hear from. It's clearly an inequitable issue, Point 2. We don't believe in the absence of the jury his testimony would be very helpful to Your Honor.

The third point we would like to raise is that if Dr. Shasha, Professor Shasha, is correct in his viewpoints with regard to the prior art upon which Mr. Nusbaum relies in trying to establish materiality, then really it's irrelevant. If Professor Shasha is correct, the patent is invalid. It's not just unenforceable. It's invalid. The Court may never even have to decide that

18

issue.

And then finally, we would just like to underscore that much of his testimony is based on Professor Shasha's and therefore is cumulative to Professor Shasha's testimony and the report. And it has no really independent basis.

THE COURT: Okay.

MR. JACOBS: Let me take those in reverse order. On the last point first, what Mr. Nusbaum made clear in his deposition is that he studied the references. After all, he is a patent lawyer in this field and he was an examiner in this field. So he is experienced in evaluating references on his own. And then he confirmed his understanding of the technical content of those references with Professor Shasha. So the words are, relying in part or relying on.

In his deposition he made clear what that means is confirmed by -- in other words, I am not reading something into this reference that BEA's technical expert does not also see in this reference. But he made clear that someone who is experienced in looking at art in this field, both as an examiner and as a patent prosecutor, he was forming a judgment about that. He was forming a judgment about that for the purposes not of validity testimony, but of inequitable conduct testimony.

One of the things he had to do in analyzing

19

inequitable conduct, which is different from what a technical expert does on the merits of validity, is apply a different claim construction standard. He has to apply, he should apply, it should be applied, the broadest reasonable interpretation standard, because that's what the PTO would be basing its decisions on the prior art on in an examination context. Professor Shasha can't testify, shouldn't be testifying to a broadest reasonable interpretation. He should be applying the Court's claim construction.

What Nusbaum does that is distinct from the testimonial standpoint is a couple of things. One, he says, look, I am a patent guy, I am a former examiner, I am the former branch chief of this division. The PTO will not allow BEA to take the depositions of the actual examiners. But as a former examiner I can tell you, this prior art would have been material.

That is one level of his expertise. It can't come in through someone else because no one else is in a position to say, I know what an examiner would have thought had he been faced with this art.

He does so using this broadest reasonable interpretation standard that the PTO applies during examination. That is something else that no other expert can testify to.

20

THE COURT: I wonder how we try patent cases around here, then, Mr. Jacobs, because, as you know, being in this district all the time, none of the four judges who hear these cases routinely generally permit this type of testimony.

MR. JACOBS: The question I have for you on that, because we understood that the general category of testimony that is excluded is, here is how the Patent Office works, here are the ways it works well, here are the ways it doesn't work so well --

THE COURT: We are talking about materiality right here. Right?

MR. JACOBS: That's correct, we are talking about materiality.

THE COURT: Very skilled counsel like yourself generally have a witness who doesn't fall in the category of patent law expert, since the Court is presumed to be the patent law expert --

MR. JACOBS: Yes.

THE COURT: -- in the room that adduces those matters to the jury. We don't do it. I don't do it as a matter of routine. I am not saying simply because it's not done that it shouldn't be done. I am not hidebound on this. I am not sure your papers have convinced me that we need to do it in this case and that it isn't indeed cumulative

EXHIBIT J

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

JOHN T. HILL, et al., Plaintiffs, v. EQUITABLE BANK, NATIONAL ASSOCIATION, Defendant.	)	Civil Action 82-220 CMW

Steven D. Goldberg, Esquire of Theisen, Lank, Mulford & Goldberg, Wilmington, Delaware. OF COUNSEL: Richard I. Kovelant, Esquire and Douglas Clark Hollman, Esquire of Goldman, Kruger, Kovelant, Hurtt, Hollmann & Kaiser of Laurel, Maryland.

Attorneys for Plaintiffs.

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Attorneys for Defendant.

O P I N I O N

Wilmington, Delaware

March 3, 1987

WRIGHT, Senior Judge

Defendant Equitable Bank has filed a motion in limine to exclude the expert testimony of Professor John C. Long of the University of Oklahoma Law School. Plaintiffs propose to have Professor Long testify as to whether defendant's alleged omissions and misrepresentations were "material."[1] Defendant claims that such testimony runs afoul of Federal Rules of Evidence 702 and 704. Defendant's motion will be granted.[2]

Under Federal Rule of Evidence 702, the testimony of an expert is admissible if it will "assist the trier of fact." The expert's proposed testimony will be to evaluate the facts as alleged and determine if the bank's misrepresentations and omissions were material. Both parties apparently agree that a fact is material if it "is one that a reasonable man would attach importance to in determining his choice of action in the transaction in question. . . .[A] material fact is one that a reasonable man would deem important in determining whether or not to purchase a corporation's stock." 3 Devitt and Blackmar, Federal Jury Instructions § 98.05 (1977). The question in the instant

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[1]Plaintiffs conceded in their memorandum that it would be improper for Professor Long to testify on the issue of liability.

[2]In defendant's reply brief, defendant contended that the motion would be moot if the Court granted defendant's then pending Motion to Alter the Judgment and dismissed plaintiffs' securities claims. Even after granting this motion in part, however, the securities claims of plaintiff James Stritzinger remain. Also,

Footnote continued next page

case then becomes whether an expert's testimony concerning whether the facts omitted or misrepresented by the bank were material will assist a jury in making the determination.

In determining whether expert testimony is proper, "'there is no more certain test than the common sense inquiry whether the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the dispute.' Ladd, Expert Testimony, 5 Vand.L.Rev. 414, 418 (1952)." Notes of Advisory Committee on Proposed Rules. The question of materiality depends in large part upon the reasonable man standard. Determining what effect a particular fact would have upon the action of a reasonable man is, in all areas of the law, an area of inquiry typically belonging to the finder of fact. In S.E.C. v. Bausch & Lomb, Inc., for example, the materiality of a fact in a securities case was determined by the judge. 565 F.2d 8, 14 (2d Cir. 1977).

In securities cases, expert testimony has been allowed, but it typically has been permitted in situations where the expert testifies to a technical aspect of the securities industry, not to legal conclusions derived from the facts of a transaction.

The Second Circuit Court of Appeals elaborated on this in Marx & Co., Inc. v. Diners Club, Inc., 550 F.2d 505 (2d Cir.),

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the RICO claims of all the plaintiffs survived the Motion To Alter the Judgment. The plaintiffs will thus want to prove the predicate acts of securities fraud even though they cannot recover for the securities fraud directly.

cert.denied, 434 U.S. 861 (1977). The court upheld the admission of testimony concerning a lawyer's typical practice in fulfilling securities laws requirements but reversed admission of testimony concerning the legal requirements of the contract at issue. Id. at 509. The court noted that securities experts were sometimes appropriate in litigation but only for purposes of explaining different aspects of the industry and not for reaching a legal conclusion about certain practices. Id. at 512.[3] In short, the expert, if allowed to testify, will simply impose his judgment of what a reasonable investor should do given certain information; such a determination is precisely the decision a jury should make. "It is for the jury to evaluate the facts in the light of the applicable rule of law, and it is therefore erroneous for a witness to state his opinion on the law of the forum." Marx, 550 F.2d at 510. In the instant case, it is for the jury to evaluate the facts of omission and misrepresentation and apply them to the applicable securities law as explained by the judge. In that decisionmaking process, there is no room for an expert law professor.

Although Federal Rule of Evidence 704 abolishes the "ultimate issue rule", it does not permit an expert to replace

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3plaintiffs make much of a footnote in Marx that cites to an earlier Second Circuit opinion in which the court held an expert's testimony about "materiality" to be admissible. United States v. Cohen, 518 F.2d 727 (2d Cir. 1975), cert.denied, sub nom Deutch v. United States, 423 U.S. 926 (1977). In that case, however, both sides used experts to discuss the issue, and it was only the testimony of the second expert that was contested. Second, the witness in Cohen testified to "concepts" of materiality and not to the kind of conclusion from the facts that plaintiffs' expert will testify to here.

the judge in explaining the law to the jury. That is the core of the problem with the expert's testimony: it does nothing more than invade the province of the Court in rendering judgments on matters of law. In the course of the many opinions issued in this case, the Court has ruled several times on which of the plaintiffs' allegations, if true, would result in recovery. In essence, that is all plaintiffs' expert would be doing, albeit for only one element of the claim. At trial, it should be the Court and not an expert, to explain the law of materiality to the jury. As defendant's opening brief quite forcefully points out, the expert viewed himself as a surrogate judge. See Defendant's Opening Brief at 12. This is as true for the question of materiality as it is for the "ultimate" question of liability. In either case, the witness will be testifying that if the facts are as alleged then a certain legal conclusion results.

Defendant has cited to an impressive list of authority prohibiting a witness -- either an expert or a layperson -- to testify to the legal significance of a particular set of facts. See Tones v. City of Oakland, 758 F.2d 147 (6th Cir.1985) (prohibiting testimony by layperson that plaintiff had not been discriminated against); United States v. Zipkin, 729 F.2d 384 (6th Cir. 1984) (prohibitng bankruptcy judge from testifying to his view of the proper interpretation of the bankruptcy laws); F.A.A. v. Landy, 705 F.2d 624, 633 (2d Cir.), cert.denied, 464 U.S. 895 (1983) (proper exclusion of former Federal Aviation Administration official's understanding of certain Federal Aviation Regula-

tions); Christian v. National Savings & Trust Company, 683 F.2d 520, 529 (D.C. Cir. 1982) (proper exclusion of lay legal conclusion about a "fiduciary relationship"); Strong v. E. I. du Pont de Nemours, Inc., 667 F.2d 682, 685-686 (8th Cir. 1981) (proper exclusion of testimony finding warnings "inadequate" and product "unreasonably dangerous").

These cases all indicate the basic principle that it is the function of the trial judge to determine the law of the case. Zipkin, 729 F.2d at 387. In this case, it is this Court's function to explain to the jury the legal meaning of materiality. It will then be the jury's function to apply the facts to the judicially explained law. Expert testimony on this issue will be superfluous and will therefore be excluded.

An Order will enter in conformity with this Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JOHN T. HILL, et al., Plaintiffs, v. EQUITABLE BANK, N.A., Defendant.	)	Civil Action 82-220 CMW CONSOLIDATED

O R D E R

This 3rd day of March, 1987, for the reasons set forth in the accompanying Opinion,

IT IS HEREBY ORDERED that Defendant's Motion in Limine is granted.

UNITED STATES DISTRICT CT. JUDGE